University of Alberta

A Comparison of Weekly Contisol G Irrigations to Saline Irrigations Versus Indwelling Catheter Changes

by

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Abstract

Objective: To examine recruitment strategies and test procedures planned for a multicentre randomized controlled trial comparing weekly irrigations with Contisol G to saline irrigations versus insertion of a new urinary catheter.

Study Design and Setting: This descriptive pilot study was conducted in a long-term care setting.

Data reported: The data reported included the recruitment strategies, study procedures for making group comparisons, dipstick urinalysis testing, descriptions of catheter blockages, incidence of symptomatic urinary tract infections, resident comfort, and costs of medical supplies and nursing time.

Conclusions: The experiential knowledge gained from this pilot resulted in the refinement of the parent study's protocols and highlighted many of the challenges other researchers encounter when conducting clinical research with this population in a nonacademic setting. The study was not intended to test the efficacy of the protocols nor can conclusions can be drawn about these products based on this study.

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CHAPTER 1:

INTRODUCTION

Background information on the use of indwelling urinary catheters (IUCs) and common complications associated with the use of catheters is discussed in chapter 1. This chapter also provides a description of the research problem, the background and significance of the problem, the context and purpose, the objectives of the pilot, and an overview of the thesis.

Research Problem

IUCs are used in healthcare settings and in the community for a variety of reasons that include urinary retention associated with bladder outlet obstruction, neurogenic bladder, delayed healing of a high stage pressure ulcer where urinary incontinence is contributing to a lack of healing, and palliative situations where care is compromised by pain or other issues (Gammack, 2002; Gray, 2001). A common complication of the long-term use of IUCs ($\geq$ 30 days) is blockages resulting from deposits of mineral salts or encrustations on the catheter surface (Kohler-Ockmore & Feneley, 1996). Numerous factors are thought to contribute to the rate of the development of encrustations in IUC (Getliffe, 1994a; Getliffe, 1994; Kohler-Ockmore & Feneley, 1996). However, the key etiology is bacterial colonization which is reported to be present after 30 days in 100% of patients with an IUC (Saint, 2000). IUC blockages that result from encrustation are associated with pain, psychological distress, urinary tract infections (UTIs), urinary catheter bypassing, a reduction in the quality of life, and increased healthcare costs (Kennedy, Brocklehurst, & Lye, 1983). Catheter-related UTIs have been associated with prolonged hospital stays and increased risk of mortality (Elliot, Reid, Gopal Rao, Rigby, & Woodhouse, 1989; Ackerman & Monroe, 1996).

Background and Significance of the Problem

Complications associated with long-term IUCs are distressing to the individual and caregivers and costly to healthcare facilities. The most frequent and problematic complications are UTIs and catheter encrustations caused by struvite (magnesium ammonium phosphate and calcium phosphate crystals). The prevalence of encrustations with subsequent blockages in catheterized individuals is at least 40%-50%. Prevention strategies have included frequent catheter changes, attempts to acidify urine orally or by catheter irrigations, increased oral fluids, and use of alternate catheter materials. None have shown notable benefit in increasing catheter life or decreasing infection. In Alberta the predominant nursing practice to manage recurrent IUC blockages is to intermittently irrigate the catheter with normal saline and/or to change the catheter after standard intervals or when there is evidence of blockage within the lumen of the IUC. More recent in vitro studies suggest that Contisol G, a commercially developed acidic solution, has the potential to reduce encrustations. Although irrigating IUC with Contisol G is not common practice in Alberta, this intervention is widely used in the United Kingdom to delay encrustation and extend catheter life (Pomfret, Winder, & Doherty, 2002). However, a systematic study comparing Contisol G irrigations or normal saline to routine catheter changes in a clinical setting has not been conducted. In addition, very little data are available that compare the costs associated with each of these interventions.

Context and Purpose

The pilot study reported in this thesis (Appendix A) was conducted within the context of a research project funded by the Alberta Heritage Foundation for Medical Research (AHFMR) and led by Dr. Katherine Moore, principal investigator. This study, *Evaluation of Weekly Catheter Irrigations With Contisol G or Saline Versus Catheter Changes Alone in Patients with Long Term Indwelling Catheters*, is referred to as the *parent study* throughout the thesis. The sample for the parent study was drawn from English-speaking individuals over the age of 18 in Edmonton and Calgary with an IUC in situ 30 days or longer and history of encrustation-related blockage problems. The sample specifically identified for the pilot study was drawn from a continuing care facility with a population of frail elderly residents with multiple co-morbidities, often including dementia and/or sensory deficits and physical disabilities. Researchers who study this population often refer to the challenges of conducting clinical studies with them. Therefore the broad purpose of this pilot study was to identify and resolve issues related to the recruitment of subjects; communications with residents, families, and staff; and the collection of clinical data. Data relevant to the objectives of the parent study are reported and discussed in relation to the published literature on the irrigations of IUCs. The process for implementing the research protocol in the clinical environment of a continuing care centre is also described. It was expected that experiential knowledge gained through this pilot would facilitate the refinement of the clinical protocols for the parent study. Appendix A illustrates the relationship of the pilot study to the parent study and the role of the student researcher to the principal investigator and a research manager of the parent study.

Objectives of the Pilot Study

The purpose of this study is to add to the nursing knowledge on the most cost-effective care of long-term IUCs in a sample of residents with a history of catheter blockages residing in a continuing care centre. This pilot study was designed to achieve the following objectives: (a) to examine the procedures for resident recruitment used for the larger study; (b) to test the procedures planned to compare residents assigned to one of the two intervention groups (catheter irrigations with Contisol G or normal saline) with subjects in a control group (standard practice, the insertion of a new catheter) when blocked and not draining urine during an eight-week period. The outcomes included the frequency of catheter blockages, the reported level of comfort before and after the interventions for blockages, the incidence of symptoms of a symptomatic UTI, and (c) the costs of the interventions (urine catheter irrigation with Contisol G or normal saline) compared to routine care.

Overview of the Thesis

In chapter 1 the background and significance of the problem of encrustations in IUCs is discussed. This complication is being addressed in the parent study, a funded multicentre, randomized controlled trial, which provides the research context for the pilot study reported in this thesis. Chapter 2 contains a review of the literature on common clinical issues associated with long-term indwelling catheters and a description of the current evidence in managing this nursing problem. IUC topics discussed are mechanisms that lead to encrustations and blockages, key factors thought to increase or accelerate encrustations, complications associated with IUC, and interventions to reduce catheter encrustations. In chapter 3 the method, objectives, sampling technique, and setting of this study are described. A description of gaining entry and soliciting study support, the recruitment process, the pilot study procedures, the instruments used for subject screening and the outcome measures, the data collection and screening, the data preparation and analysis, the ethics approval process, the risk of participation. and definitions are covered as well in this section. Chapter 4 presents the results of the key objectives, which are (a) to examine the procedures for resident recruitment and (b) to test the procedures planned to compare residents assigned to one of the two intervention groups (urine catheter irrigations with Contisol G or normal saline) with subjects in a control group (standard care, the insertion of a new catheter) over eight weeks. An interpretation of the results of the pilot study with support from the current literature and the implications of the results from the larger study are presented in chapter 5.

CHAPTER 2:

REVIEW OF THE LITERATURE

Literature Search

The literature was reviewed to gain a fuller understanding of the causes of blockages in IUC, the interventions used to minimize the problem, and the gaps in knowledge on the use of irrigation solutions to treat or minimize encrustation and blockage.

The purpose of this comprehensive literature review was to identify articles relevant to the key concepts included in the study objectives. The search terms used were *IUC*, *management of IUCs*, *causes of blockages in IUC*, *catheter maintenance solutions*, *catheter care*, *Foley catheter*, *complications in IUC*, *urinary bypassing*, *indwelling catheters*, *caring for long-term catheters*, and *irrigation of IUCs*. The database search included Best Evidence, CINAHL, Embase, Medline, Cochrane Library, and Academic Search Premiers. Because evidence-based practices and rigorous research had started to evolve only around 1985, the date 1986 was selected as the earliest date to capture practice changes and research in catheter care. The search was limited to articles published in English between 1986 and 2005 and resulted in 7,380 articles. The primary screening of articles by title and abstract resulted in 73 articles. A hand search of reference lists resulted in the retrieval of an additional 20 articles on this topic. Of these articles, 36 were excluded and 57 included; 37 were research articles and 20 were review articles (Appendix B). Although a substantial number of review or prescriptive articles on the topics were located, few research articles specifically addressed IUC irrigations. None of the research studies evaluated the effectiveness of Contisol G in a clinical setting.

Mechanisms That Lead to Encrustations and Blockages

Encrustations are a leading cause of blockages in IUCs. They are collections of calcium phosphate, bacteria, glycocalyx, protein, precipitated crystals, magnesium, and ammonium phosphate salts (Evans, Godfrey, & Fraczyk, 2001). A key factor is bacterial colonization that result in biofilms.

Bacterial Colonization

Within 72 hours of catheter insertion, 44% of patients with IUCs will have significant bacterial colonization, and by 30 days 100% will be colonized (Saint, 2000). Bacteria such as *proteus mirabilis, pseudomonas aeruginosa, providencia*, and *klebsiella* cause the urine pH to become alkaline, which contributes to the formation of encrustations (Gray, 2001; Hallson & Rose, 1989). Substances adhere to the lumen and impede the flow of urine, which causes partial or complete catheter obstruction. Particular types of bacteria such as *proteus mirabilis* alter the pH level by causing the urea in the urine to form ammonia salts. The raised pH can lead to the increased formation of crystals of struvite and hydroxyapate (calcium phosphate) that adhere to the external and internal surface of the catheter (Evans et al., 2001). Kunin, Chin, and Chambers (1987) found that 40% of a group of 50 subjects experienced encrustation with or without subsequent blockage when an IUCs remained in place for 30 days. Getliffe (1994) found that the rate of encrustation in IUCs is over 50% and that certain patients are prone to repeated encrustations.

Biofilm Development

Once an IUC has been inserted, the pathogenesis of bacterial colonization and the evolution of bacteriuria and UTI are complex. A thick biofilm is formed when specific types of bacteria colonize on or in the catheter (planktonic phenotype is a type of bacteria genetically predisposed to adhering to surfaces such as a bladder or catheter wall). This biofilm is a glue-like substance made up of oxalate crystals. Bacteria adhere to the crystals, which leads to encrustations that eventually block urine drainage through the catheter (Esclarin, Garcia, Heruzzo, & Cabrera, 2000; Fuqua & Greenberg, 1998; Stickler, Morris, Moreno, & Sabubba, 1998; Sabbuba, Hughes, & Stickler, 2002). The bacterium rapidly multiplies throughout the catheter, forms a complex structure with a circulatory system, provides nutrients to bacteria in the biofilm, and removes waste (Morris et al., 1999; Stam, 1991). Once established, the biofilm gradually hardens, crystallizes, and obstructs the catheter eyes and lumen (Stickler et al., 1993; Stickler et al., 2003). With sufficient blockage the catheter is unable to drain, and urine either bypasses the catheter and causes incontinence or can reflux into the ureter and causes pyelonephritis.

Risk Factors for Encrustations

Length of Time a Catheter Remains in Situ

One factor that impacts the risk of infections and encrustations may be the length of time that a catheter remains in place. Darouiche et al. (1999) found that after a catheter had been in situ for seven days, 40% of the urine cultures were positive in a group of men with IUCs following radical prostatectomy, and 84% of the cultures were positive after 14 days, an increase of 50%. Others reported that the prevalence of UTIs among patients with short-term catheters (< 30 days) varies from 5% to 20%, with the risk of a symptomatic bacteriuria among those with long-term catheters (> 30 days) as high as 100% (Liedl, 2001; Sedor & Mulholland, 1999; Wong, 1983). No studies were found that correlated the length of time in situ of the IUC with the development of encrustations.

Catheter Composition

Catheter composition and size are thought to be factors in the development of encrustations and subsequent blockage (Becker, 1993). Kennedy et al. (1983) and McGill (1982) found that patients with size 18 French catheters or larger had a higher incidence of leakage and blockage problems. Catheters designed for long-term use are usually pure silicone, silicone coated, or hydrogel-coated latex. Silicone elastomer coated latex catheters have smoother surfaces and consequently could result in fewer problems with encrustation (Bull, Chilton, Gould, & Sutton, 1991; Henderson, 1999). However, Roberts, Kaack, and Fussell (1993) reported no difference in the adherence of bacteria to the hydrophilic surface of catheters compared to silicone catheters.

Urine pH

The major components of encrustations are substances such as struvite and calcium phosphates, which develop in alkaline urine (Cox & Hukins, 1989; Hedelin, Bratt, Eckerdal, & Lincoln, 1991). Microorganisms such as *proteus mirabilis* generally found in the normal flora of the bowels commonly produce the enzyme urease. This enzyme contributes to the breakdown of urine urea, which releases ammonia, resulting in increased alkalinity of urine. Burr and Nuseibeh (1997) have shown that catheters block frequently when the urine pH is high. Individuals with a pH greater than 6.8 had 10 times greater precipitation than did individuals (nonblockers) with a pH lower than 6.8

(Hedelin, Grenabo, & Petterson, 1991; Mathur, Suller, Stickler, & Feneley, 2006). King and Stickler (1991) found that urine pH returns to the original pH level within two hours of washout with acidic catheter maintenance solutions, which suggests that intermittent acidifying of the urine, may not prevent encrustations.

Open System Versus Closed System

The interruption or opening of the catheter system increases the risk of a symptomatic UTI and/or acute or chronic pyelonephritis (Nicolle, 2001; Wong, 1983). Pien and Landers (1983) studied the incidence of bacteriuria in a group of 90 subjects who were undergoing catheterization in an acute care setting. They found bacteriuria developed within 72 hours in 19 out of 21 subjects (23%) with a closed drainage urinary system and suggested that these infections likely occurred because of contamination during catheter insertion. Mulhall, King, Lee, and Wigginton (1993) reported that opening a closed system urinary drainage system during routine care contributed to increased bacteriuria in patients who had had catheters for 14 days or less.

Complications Associated With IUCs

Risks Associated With Blockages

Common complications associated with the use of an IUC are bypassing of urine around the catheter, urethral irritation, urinary calculi, urethral erosion, and dislodgement of the catheter, which causes urethral lacerations and bleeding (Pomfret, 2000; Warren et al., 1994). Risks can be further increased with longer durations of catheter insertion, nutritional status, age, gender, co-morbid conditions, concomitant infections, systemic antibiotics, the type of drainage system, and trauma (Tenney, 1987). These factors all contribute to an increased risk for bacteriuria, UTIs, and encrustations. There are many opinions on the risk factors associated with catheter-related problems. For example, Getliffe (1994) suggested low fluid intake, an alkaline pH level of urine, poor mobility, and being female as possible risk factors for IUC blockages. Some individuals seem more resistant to obstructions and require less frequent changes, whereas others have a higher urine pH level; excrete more calcium, protein, or mucin; and are consequently more prone to encrustation formation, blockages, and thus frequent catheter changes (Cravens & Zweig, 2000; Kunin et al., 1987). It is unclear based on the current evidence whether these risk factors increase encrustations or cause other types of blockages (without encrustations). Evans et al. (2001) recommended changing the catheter prior to the blockage as the most effective intervention and planning catheter changes based on individualized needs, the blocking pattern, and the characteristics of the patient rather than scheduling monthly changes or using standard generic catheter protocols.

Catheter-Associated Discomfort

Roe and Brocklehurst (1987) showed that 27% of patients experienced discomfort from their catheters, 25% experienced pain, 11% described the pain as extreme, 61% found that catheter changes caused discomfort, and 36% did not experience any pain or discomfort associated with their catheters. This qualitative study involved 36 subjects, and the authors reported that those with a size 18 Charriere catheter were the most likely to experience pain, that those who were the most mobile had the least amount of pain, and that males reported discomfort more frequently. Thirty-two of the subjects experienced leakages at least weekly, and 23 had experienced blockages. Wilde (2002) interviewed 14 subjects with long-term IUCs and found that 10 subjects experienced catheter-related pain. Four of the subjects felt that the nursing staff were not knowledgeable or did not seem concerned about the pain caused by the catheter.

Bacteriuria

The incidence of bacterial colonization with an IUC is approximately 5% per day and is considered inevitable when the catheter remains in place over a prolonged period of time (Liedl, 2001). Saint (2000) found that within 72 hours 44% of patients with IUCs will have significant bacterial colonization, and by 30 days 100% will be colonized. *Asymptomatic bacteriuria* is bacterial growth in the urine without symptoms. The presence of bacteriuria may become clinically relevant because of the risks of a symptomatic UTI (Liedl, 2001; Warren, Muncie, Hebel, & Hall-Craggs, 1994). *Symptomatic bacteriuria* or a *symptomatic UTI* refers to local or systemic symptoms such as nausea, flank pain, pyuria, restlessness, cloudy urine, confusion, and/or fever (Cravens & Zweig, 2000; Saint & Lipsky, 1999). Clinical manifestations associated with UTI may include catheter bypassing, suprapubic discomfort, or haematuria. Catheter-associated infections also impact the upper urinary tracts and increase the risk of acute and chronic pyelonephritis, parenchymal scarring, and urosepsis. Forty percent of the nosocomial UTIs in clinical settings are attributed to IUCs (Brennan & Evans, 2001; Kohler-Ockmore & Feneley, 1996). Catheter-associated UTIs (CAUTIs) are the most common nosocomial infection in nursing homes and hospitals and increase institutional death rates (Maki & Tambyah, 2001). Not only are CAUTIs a significant burden for the patient, but they are also costly for healthcare facilities (Maki & Tambyah, 2001). Catheter-related UTIs in the USA have been shown to cost a minimum of $676 extra per patient stay, and catheter-related bacteremia can cost up to $2,836 per patient stay (Saint, 2000).

Nursing Interventions to Reduce Catheter Encrustations

Numerous interventions have been proposed to reduce encrustations and blockages; however, there is no evidence to substantiate their effectiveness. Strategies such as increasing hydration and using alternative materials for catheter construction such as silicone and hydrogels have not reduced the colonization of urease-producing bacteria and subsequent encrustations in either the laboratory or clinical setting (Cox, Harries, Hukins, Kennedy, & Sutton, 1987; Hukins, Hickey, & Kennedy, 1983). There is no evidence to support the use of antiseptics or antimicrobial-impregnated catheters to reduce bacteriuria in long-term IUC (Riley, Classen, Stevens, & Burke, 1995). Verleyen, DeRidder, Van Poppel, and Baert (1999) showed that a silver alloy catheter was initially resistant to bacterial colonization of the urine in a study with 215 patients, although this resistance was negligible after two weeks. Oral antibiotics have not eliminated the biofilm formation on long-term IUCs or reduced the subsequent risk of encrustation. Even when treated with antibiotics, based on the urine culture results, some organisms survive the therapy and consequently proliferate as soon as treatment is discontinued. Costerton, Stewart, and Greenberg (1999) offered three possible theories to account for bacterial resistance to antibiotic therapy: (a) the antibiotic may not completely penetrate the biofilm, (b) some bacteria within the biofilm survive in a near-starvation mode and may not be killed by antibiotic treatment, and (c) specific aspects of the biofilm are mediated by gene expression, which may alter its sensitivity to antibiotics.

Solutions for Irrigating Indwelling Catheters

Irrigating the catheter with normal saline to prevent or clear blockages or bypassing urine has created confusion in nursing practice because there is no evidence to support the practice (Gates, 2000). Some research has suggested that routine catheter irrigation in long-term IUCs may have some use, but further research is required to confirm the effectiveness in a clinical setting. In a review of the literature, Kennedy et al. (1983) found descriptions of the use of irrigation solutions for blocked IUCs confusing and inconclusive. Roe (1989) surveyed 106 nurses on catheter irrigations, and 28% recommended using this intervention on patients with a history of catheter use, and 33% recommended it as routine catheter care. Half of these nurses could not provide any rationale or evidence on which to base this practice aside from following the manufacturer's instructions on the use of irrigation solution. A decade later Kennedy, Brocklehurst, and Faragher (1992) noted that routine irrigations continued to be used without a thorough assessment and clear identification of the clinical issues or their persistence. Some research suggested that saline irrigations have not been highly effective in maintaining catheter patency or reducing blockage and that more research is needed to define who would in fact benefit from this type of intervention (Evans, Godfrey, & Feneley, 2001).

Both Ruwaldt (1983) and Gates (2000) found that saline irrigations reduced the incidence of catheter blocking but suggested that the procedure is costly and time consuming. In vitro evidence of acidic bladder irrigations such as Contisol G rather than saline irrigations has shown a reduction in encrustations and blockages in a model bladder (Getliffe, 1994; Getliffe, Hughes, & Claire, 2000). However, this solution has not been systematically evaluated in clinical settings. See Appendix C for literature chart on irrigations.

Volume of Solution for Irrigations

Getliffe et al. (2000) conducted a study under controlled laboratory conditions to examine the optimal volume of acidic irrigation solution required to dissolve catheter encrustations. Using a bladder model, they compared 100 mls irrigation with 50 mls using a colorimetric analysis of the magnesium and calcium content of the solution following the irrigation. They found 50 mls of irrigation solution to be as effective as 100 mls in a sample of 24 vials of urine obtained from four volunteers.

Summary of Literature Review

Complications associated with long-term indwelling catheters are distressing to individuals and caregivers and costly to healthcare facilities. The most frequent and problematic complications are UTIs and catheter encrustations caused by struvite (magnesium ammonium phosphate) and calcium phosphate crystals. The prevalence of encrustations with subsequent blockage is at least 40%-50%. There is insufficient evidence to support routine catheter changes or catheter irrigations to manage this complication. Some more recent in vitro studies suggest that Contisol G, a commercially developed acidic solution, has the potential to reduce encrustations. However, no systematic studies were found that compare the effectiveness of this solution in the clinical setting or compare it to irrigation with normal saline versus standard practice, the insertion of a new catheter, if a blockage occurs. In addition, little data were available on comparisons of the costs associated with each of these interventions. There has been no systematic clinical evaluation of interventions to prevent IUC blockages. The range of factors such as balloon size, types and amounts of fluid to fill the balloons, catheter size, irrigation solutions, length of time the solution is left in the bladder, frequency, and various settings (home care, long term care, acute care) contribute to some of the difficulties in comparing the existing data or applying the findings to current practice.

CHAPTER 3:

METHOD AND RESEARCH DESIGN

In this chapter the method, objectives, sampling technique, and setting of this study are described. This section is followed with a description of gaining entry and soliciting study support, the recruitment process, the pilot study procedures, the instruments used for subject screening and outcome measures, data collection and screening, data preparation and analysis, the ethics approval process, and the risk of participation. The chapter concludes with a list of the definitions of terms.

Method

A pilot study was undertaken to test planned recruitment procedures in preparation for a larger study. An experimental pre-post design was used to examine cost-effective interventions for reducing blockages caused by encrustations in long-term IUCs. The study subjects were randomly assigned to one of three groups: (a) the Contisol G irrigation group, (b) the normal saline irrigation group, and (c) the standard practice (control group). The pilot study was confined to a long-term care centre in Edmonton between May 1, 2005, and August 31, 2005.

Objectives

The specific objectives of the pilot study were twofold: (a) to examine the procedures for resident recruitment and (b) to test the procedures planned to compare residents assigned to one of the two intervention groups (urine catheter irrigations with Contisol G or normal saline) with subjects in a control group (standard practice, the insertion of a new catheter) during an eight-week period on (a) dipstick urinalysis (urine ph, leukocytes, nitrites & haemoglobin); (b) visual description of catheter encrustations and blockages; (c) the reasons for catheter changes, (d) the incidence of symptomatic UTI, (e) the reported level of comfort, and (f) the direct cost of medical supplies and nursing time.

Sampling Technique

Convenience sampling was used to recruit subjects who met the following inclusion criteria: > 18 years of age, English speaking; cognitively alert (i.e., had a Mini Mental State Examination [MMSE] score ≥23), had an IUC for a minimum of 30 days, and had a history of catheter blockage problems (for example bypassing of urine and/or encrustation blockages). The potential subjects also had to be willing to consent to participate in the study or have agents who would provide consent in writing on their behalf. The exclusion criteria were symptomatic bacteriuria, a fever ≥ 38°C, known bladder pathology, radiation or interstitial cystitis, impaired renal function (creatinine ≥ 2.0 mg/dl), gross haematuria, continuous bladder irrigations, and/or allergies to a hydrophilic-coated or a latex catheter.

Setting

The study took place in an urban setting in a large long-term care centre. The centre has 14 nursing units and serves 430 residents. The size of the units ranged from 22 to 50 residents per nursing unit. The majority of the population in this setting were frail elderly adults with multiple co-morbidities, dementia sensory deficits, and physical disabilities that required 24-hour nursing care. The staffing component per unit consisted of a resident manager (a registered nurse), a team leader (a licensed practical nurse), and two to four nursing attendants during the day shifts. Other interdisciplinary staff included part-time support from the following: unit clerks, physiotherapists, recreational therapists, recreational attendants, dieticians, occupational therapists, a social worker, a clinical nurse specialist, and two nurse educators. During the evenings two resident managers covered the facility, a licensed practical nurse was in charge on each unit, and two to three nursing attendants were on each unit. This staffing mix was further reduced for the night shift.

Gaining Entry and Soliciting Study Support

The recruitment strategy for this study included discussing the study with staff and the management team to obtain their support, providing inservices to staff, posting a recruitment advertisement on the Internet, and placing posters (Appendix D) with the student researcher's contact numbers (phone number, pager number, and e-mail address) on nine units and in public sitting areas and the lobby in the long-term care facility. Additionally, an introductory overview of the research project was provided to the management team and the medical director at the facility. A preparatory letter with a brief overview of the study was given to each unit manager along with an information sheet for the professional and nonprofessional staff on each unit (Appendix E). At each inservice handouts were also provided to staff to share with their colleagues who were unable to attend.

Sample Recruitment, Selection, and Assignment

The resident care manager or team leader approached all residents on the unit who met the study eligibility criteria to gain permission for the student researcher to describe the study to them and invite their participation. The student researcher provided written and verbal information about the study to the potential subject or his/her agent and obtained signed consent (Appendix F). Each study subject's attending physician was notified in writing about his or her resident's enrolment in the study. The study manager used a randomization/blinding process to assign each subject to one of the three study intervention groups (Contisol G, normal saline, or control) using randomization/blinding process would. The research manager at the research centre randomly selected the allocation sequence for each intervention group from numbered, sealed envelopes based on a computer generated list. Inside each envelope was a label with one of the three interventions on it. The subject was then provided with a number to identify him or her in the study and to ensure confidentiality and was allocated to one of the three study intervention groups (Contisol G, normal saline, or control) according to the selected label.

Instruments Used for Subject Screening and Outcome Measures

The potential subjects were screened for mental competence using the MMSE. Outcome measures included urinalysis dipstick tests, measures of comfort, and indicators for UTIs. The instruments used to screen the potential subjects and assess subjects who met the criteria on outcomes are described below.

Mini Mental State Examination

The MMSE was selected as a practical and standardized method of assessing the cognitive function of potential subjects. This widely used tool has been tested for both reliability and validity and has been employed primarily to screen residents with cognitive impairment deficits, to identify dementia, and to follow cognitive progression over time. A score of 23 or greater is considered normal cognition, and a score below 23 may be indicative of mild cognitive impairment and/or dementia. Residents with a score of 23 or greater on the MMSE were invited to participate in the study.

Urine Reagent Strips

Urine pH levels were measured with the Bayer Multistix® 8 SG, a reagent strip used for urinalysis. The urine was collected from the catheter using sterile technique, and the pH was tested after the insertion of a new catheter on day 0 and weekly for each subject. The Bayer Multistix® 8 SG reagent strip was read 60 seconds after being dipped into the urine sample as per the manufacturer's instructions. Subjects who were receiving irrigations had their urine tested one to five minutes before the irrigation procedure and immediately following the irrigation procedure. The results could range from 5.0 to 8.0. For the purpose of this study a urine pH of 6.6 or greater was considered alkaline.

All subjects' urine leukocytes, nitrites, and haemoglobin levels were measured weekly using the Bayer Multistix® 8 SG. Subjects assigned to the irrigation group were tested before and after irrigations. The urine was collected and tested in the same manner as discussed under pH levels above. The leukocyte results could range from negative to large amounts. Any results above negative were considered a positive level. Nitrites were measured as either negative or positive. Haemoglobin results could range from negative to large amounts. Any measurement above negative was also considered a positive level.

Comfort Descriptors

Two questionnaires, the Catheter Surveillance Questionnaire (Appendix G) and the Catheter Irrigation Questionnaire (Appendix H) were used to measure comfort. Both instruments were developed for the larger study based on the current literature. Content validity of the questionnaires was established by a group of nurse experts in continence care. The language of the questionnaires was rated at a Grade 6 level.

On day 0, following the insertion of the study catheter, the investigator asked the subject to complete the Catheter Surveillance Questionnaire. This instrument, which was used to measure the subject's comfort level with the catheter change, is comprised of five items. The subjects are directed to rate their responses to the first item, "your bladder comfort before catheter change," as *good, acceptable* or *unacceptable*. The next three items explore comfort: during catheter insertion, 15 minutes later, and two hours after the catheter change. The subjects are asked to rate their responses as *good, acceptable*, or *unacceptable*. The last question asks the subjects to rate their satisfaction with the current catheter program. Those who were receiving irrigations completed the Catheter Irrigation Questionnaire, which is comprised of six items, and rated their responses to the first item, "your bladder comfort before irrigation," as *good, acceptable* or *unacceptable*. The next three items explore comfort during catheter irrigation: when the solution "was felt in the bladder," "after having the solution swished in and out" of the catheter, and "two hours after the irrigation was completed." The fifth question asks the subjects to rate their satisfaction with the catheter program. They are directed to rate their responses to items 2 through 5 as *good, acceptable*, or *unacceptable*. The last item requires a *yes* or *no* response to the question "Would you recommend the bladder irrigation?"

Urinary Tract Infection (UTI)

Once each week the student researcher reviewed the nursing documentation, the physician's orders, the laboratory results, and the medication administration record (to check for the addition of any antibiotics) for any evidence of a symptomatic UTI. The residents who met the following criteria were defined as having a UTI: bacteriuria $\geq 10^2$ CFU/ml and at least one of the following symptoms: fever, autonomic dysreflexia, increased spasticity, comfort or pain over the kidney or bladder or during urination, onset/increase in incontinence episodes, cloudy urine with increased odour, malaise, lethargy, or sense of unease (National Spinal Cord Injury Statistical Center, 1992).

Data Collection Procedures

The data-collection procedures for this pilot study were comprised of three steps (Appendix I), each of which is described below.

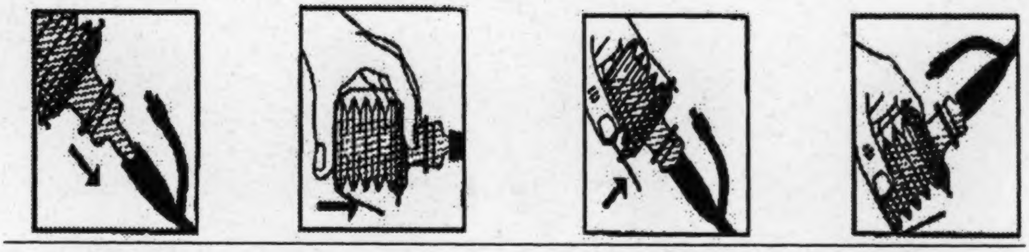
Step 1: Baseline demographic and clinical data were obtained from the subject's medical record: age, gender, diagnosis, and MMSE score within the last three months. The chart was also reviewed for the catheter history, which included the reason for catheterization, the date of catheterization, the catheter size, the balloon size, the amount of fluid used to fill balloon, the frequency of bypassing, the frequency of blockages, and the dates of catheter changes. The student researcher administered the MMSE to the subject if it had not been done within the last three months. Residents who received a score ≤ 23 were thanked for their contribution and informed that their role in the study was complete, and those with a score ≥ 23 continued with the study.

Catheter interventions for each subject enrolled in the study began the next time that the subject required an IUC change and continued for eight weeks or until he or she had undergone a maximum of three additional IUC changes. The maximum of three additional IUC changes was based on the observation that, on average, individuals with a history of IUC blockages require catheter changes every one to two weeks. An additional three catheter changes is expected to be the minimum number of subsequent changes if the interventions had no effect. The indicators for an IUC change due to blockages are bypassing of urine, no urine output in the catheter bag in a four-hour period, or both. All subjects had a new IUC inserted if a blockage or bypassing of urine occurred during the study period. The staff were also instructed to refrain from irrigating catheters on subjects enrolled in this study and to call the student researcher if they had any questions regarding this practice change or other study questions.

Step 2: The next time that a subject's IUC required changing, day 0, the student researcher inserted a standardized Bard® lubricious coated sterile urinary catheter with a 5 cc balloon using a standard IUC sterile insertion technique. The student researcher then cleaned the sample port of the drainage tubing (attachment of the catheter bag) with an alcohol swab, waited for it to dry, and removed a small sample of free-flowing urine from the port using a sterile syringe. The urine was placed in a disposable cup and tested with a urinalysis reagent strip (Bayer Multistix® 8 SG). The urine was tested for the leukocyte, pH, haemoglobin, and nitrite levels as per the manufacturer's instructions. Each subject was asked to complete the Catheter Surveillance Questionnaire following this initial IUC insertion and any subsequent changes by the student researcher (maximum of three) during an eight-week period. The student researcher timed the procedure with a wristwatch to estimate the amount of time that it took to carry out the entire catheter insertion. The start time was recorded as the time at which the student researcher set up supplies in the subject's room in preparation for the IUC change, and the finish time at the time at which the student researcher completed the IUC change, including testing the urine with the reagent strip.

Step 3: On a weekly basis during the study, the student researcher reviewed the chart for catheter blockages, bypassing of urine, catheter changes, or the development of a symptomatic UTI. She visually inspected the catheter, drainage tubing, and catheter bag each week for any signs of encrustations, bypassing, and sediment and gently palpated the catheter for gritty or coarse sediment within the lumen. The student researcher tested a sample of urine using a urinalysis reagent strip as described above. If an IUC was assessed as blocked, it was changed following the procedure outlined in step 2. The IUCs of subjects assigned to an irrigation intervention were then irrigated with Contisol G or saline according to the manufacturer's instructions on the use of the prepackaged irrigation solutions. For this study, catheter irrigation involved the gentle instillation of 50 mls of sterile Contisol G or sterile normal saline at room temperature into the catheter over a period of 60 seconds using sterile technique. The solution remained in the catheter and bladder for 1-2 minutes. The single-use bellows type of unit containing Contisol G or saline was compressed to allow gentle, controlled agitation of the solution into the catheter and bladder. Small amounts of this solution mixed with urine would then gradually drain back into the original irrigation container with each compression of the bellow unit (Figure 1).

The student researcher timed the irrigation procedure. The start time was recorded as the time at which the materials were gathered for the irrigation. The finish time was recorded at the time at which the irrigation procedure was completed, including the urine testing with the reagent strip. Following the IUC irrigation, a second sample of urine was tested using the reagent strip, and then the subjects assigned to the irrigation procedure were asked to complete a comfort questionnaire.



The nozzle of the container was inserted into the catheter.

The container neck was held between first and second fingers and the bottle squeezed by pressing on the base with the thumb, providing a controlled flow into the catheter without the introduction of excess air.

Gently pressing and releasing the bellows continuously for one minute achieved a controlled flushing action.

On the completion of the 60 seconds, the drainage was drained back into the container. The catheter was then connected to the drainage bag and the solution discarded in the toilet.

Figure 1. Procedure for irrigating with either normal saline or Contisol G.

Step 4:: Step 3 was repeated weekly for a total period of eight weeks or until there were a maximum of three catheter changes. In the eighth week, the subjects who had not undergone an IUC change since week 0 had their IUC changed following the procedures outlined in step .

Data Preparation and Analysis

Descriptive statistics were used to summarize the demographic (gender, diagnosis, mobility, MMSE, and age) and clinical characteristics (urinalysis using the reagent strips, blockages during the study period, symptomatic UTI) of the study sample. Nominal data (e.g., gender) were summarized using frequencies and percentages; continuous data (e.g., age) were summarized using frequencies, means, and medians.

To address the first objective, all subjects who met the eligibility criteria between May 1 and August 31, 2005, were invited to participate in the study. The frequency and percentages of the residents who agreed to participate, declined, or withdrew were calculated. Subjective narrative descriptions were used to summarize recruitment strategies, challenges that arose during the recruitment process, and strategies used to resolve issues.

To address the second objective, analysis of variance and Chi square procedures were planned to compare the groups on the continuous variables (frequency of catheter blockages, incidence of symptomatic UTIs, and direct costs of nursing time and supplies) and on the nominal variables (comfort levels), respectively. The alpha level was set at 0.05.

Ethical Approval and Protection of Human Subjects

Ethical approval was a three-stage process. It was first received through the Health Research Ethics Board at the University of Alberta. Second, facility approval was obtained through the site-management team, which included the director and vice president of the long-term care facility; and third, approval from the tri-site Caritas Research Steering Committee was received. The student researcher made herself available throughout the study to answer questions from subjects, families, and/or staff. All subjects or their surrogates were requested to sign consents (Appendix F) or to give a tape-recorded verbal consent if they agreed to be involved. They were made aware that participation was voluntary and their choice. They were informed that whether or not they participated, there would be no impact on their care and that they could withdraw from the study at any time. Special precautions to protect this population's interests involved screening for cognitive impairment such as dementia with the MMSE and including only individuals with a score of 23 or greater. Each individual who signed the consent was asked to repeat his or her understanding of the study and willingness to participate. The student researcher ensured that the subject's family (if the subject requested family involvement), the staff, and the attending physician were aware of the study by leaving a nursing note on the physician's communication sheet in the chart and verbally communicating this information to the staff and resident care manager. Information about the study and a colour poster were placed in the chart of each subject, and a neon study label (with information on the study and a contact number) was placed in the Kardex and on the outside of the subject's chart. This study label was used as a reminder to the staff that this resident was involved in the catheter study. If any of the following symptoms were experienced during the data-collection period, the physician was notified and the individual was dropped from the study: a temperature of 38°C or greater, acute bleeding, a reaction to the irrigation solution, or any other untoward symptoms.

The data collected from this study will be kept locked in a filing cabinet for five years. The consents were stored separately from the data. None of the data collected from this study will be considered for future studies unless approval from the ethics committee is received.

Risk of Participation

No adverse events were anticipated with this study. Saline irrigations of long-term IUCs were already a common practice in Canada, and Contisol G irrigations are standard practice in the United Kingdom. There were no published reports found on side effects from using Contisol G. All of the subjects were made aware that there had been no reported adverse effects, allergic response(s), or other discomforts or symptoms. If such responses had occurred, the data collection would have been concluded for that individual.

Definitions

Contisol G: Contisol G is a mild acidic solution made up of magnesium oxide, sodium carbonate, and disodium edentate. It is listed as a urologic irrigation solution in Health Canada's drug product database (Maelor Pharmaceudicals) for the dissolution of phosphatic calculi in the bladder and the reduction of encrustations on urinary catheters (Getliffe, 2003; Rew, 1999). It is contraindicated in subjects who experience acute symptomatic UTIs with haematuria and/or urothelial lesions. The magnesium is used to minimize irritation. The 50-ml sterile solution is provided in a single-use bellow container that allows for the gentle agitation of fluid into the catheter and bladder.

Normal saline: Normal saline solution is a sterile 0.9 sodium chloride solution used for irrigating the catheters. The 50-ml sterile solution was provided in the single-use bellow container to allow for the gentle agitation of fluid into the catheter and bladder.

Day 0: Day 0 was the day that each subject started the study. The subject's urine was tested, and a standard #14 or #16 hydrophilic catheter (Bard®) was inserted on a planned catheter change day. The student researcher inserted the catheter on day 0.

Urinary blockage: A urinary blockage is defined as any of the following: encrustations within the catheter that block urine flow completely, a reduction in urine flow because of encrustations or blockage, no urine output in four hours, or the bypassing of urine.

Standard catheter change: A standard catheter change is defined as the facility's protocol/procedure for changing the catheter using sterile technique. A new catheter was to be reinserted using sterile technique at the end of the eight weeks or as needed if a blockage or bypassing of urine occurred.

Symptomatic UTI: A UTI is defined bacteriuria $> 10^2$ CFU/ml and a dipstick that tests positive for leukocytes and at least one of the following symptoms: fever, autonomic dysreflexia, increased spasticity, comfort or pain over the kidney or bladder, onset/increase in incontinence episodes, cloudy urine with increased odour, malaise, lethargy, or sense of unease (National Spinal Cord Injury Statistical Center, 1992).

CHAPTER 4:

RESULTS

In this chapter the results relevant to each of the study objectives are presented. The key objectives were (a) to examine the procedures for resident recruitment and (b) to test the procedures planned to compare residents assigned to one of the two intervention groups (urine catheter irrigations with Contisol G or normal saline) with subjects in a control group (standard care, the insertion of a new catheter) during an eight-week period. The results of the data collected are presented. Descriptive statistics are used to present the outcome variables of the intervention groups. Because of the sample size, group comparisons on outcome variables using inferential statistics were not appropriate.

Sample Recruitment, Selection, and Assignment

Sampling Recruitment

A total of 18 residents from six nursing units in one large long-term care facility in Edmonton were approached to participate in the pilot study. During the four-month period recruitment period (May 1, 2005, to August 31, 2005), nine (50%) of the 18 approached agreed to participate. Of the nine who did not participate (three males and six females), three declined, and the other six did not meet the inclusion criteria. Direct comments from the residents and or/family who declined included, "Just too much going on in our life right now"; or "I do not feel like it"; or "Too much stress already; could not possibly take anything else on right now." The reasons that subjects did not meet the inclusion criteria were that they had an MMSE less than 23 (four subjects) or symptomatic UTIs and were being treated with oral antibiotics (two subjects). The two with symptomatic UTIs were followed for a minimum of three weeks to determine whether the UTI had resolved and whether they might be eligible to participate. In one case the subject's catheter was discontinued completely; in the other the individual had deceased.

Sample Selection and Assignment

The nine eligible subjects were randomly assigned to one of the three groups: Contisol G irrigation (n = 1), saline irrigation (n = 3), and no-intervention group (n = 5). Of the nine subjects, five completed the entire eight-week data-collection period, three in the no-intervention group and two in the saline group. The remaining four subjects had met the end-point critieria of the pilot. One subject withdrew before day 0 of the study ("Just did not feel like it"), one subject died unexpectedly before the second week of data collection, and two subjects required three catheter changes before the end of eight weeks, a study endpoint.

Gaining Entry and Soliciting Study Support

Following the process of gaining entry and marketing strategies described in chapter 3, the researcher held six one-on-one discussions on the six nursing units and a total of nine 30-minute inservices for staff. During the unit visits the nursing unit staff provided 16 referrals. Electronic contact (e-mail) with the student researcher resulted in the recruitment of two more potential subjects. No responses were received from the Internet advertisement or poster advertisements in the facility.

Study Procedures for Group Comparisons

Demographic Data and MMSE

The demographic and clinical characteristics of the sample are summarized in Table 1. Five females and four males were recruited, with a mean age of 71 years (range 31 to 90 years). Diagnoses and medical histories included quadriplegia, metastatic breast cancer, diabetes, prostate cancer, congestive heart failure, multiple sclerosis, chronic obstructive pulmonary disease, hiatus hernia, and other medical conditions. All subjects had more than one co-morbidity. The mobility status ranged from completely immobile and requiring a mechanical lift to a one-person assisted transfer. The MMSE scores for the subjects ranged from 25 to 30 (mean score, 26.6). In one circumstance the subject had upper-arm paralysis and aphasia and therefore had a significant amount of difficulty in responding to the format of the questions in the MMSE screening tool. However, the occupational and speech therapy staff had included extensive documentation in her medical record that confirmed her mental competency and ability to communicate through specific gestures (such as nodding up and down for *yes* or turning her head from side to side for *no*). The staff and resident care manager also affirmed that this individual was competent to participate in the study and could respond to the questions appropriately. In addition, both the subject and the subject's family indicated that they understood the intent of the study and were willing to participate. Another subject agreed to participate in the study but stated on repeated visits that she was too tired to bother with the MMSE. This individual was able to articulate the purpose of the study to staff members and the student researcher. The staff and the resident care manager felt that this individual was competent to make an informed decision on the study and to provide consent. In addition, she had complete signing authority over all of her financial and personal affairs and had no appointed agent.

Table 1

Demographics

Subject	Gender	Medical diagnosis	Medical history	Mobility	MMSE	Age	Group
1	Male	Quadriplegic C5	Diabetes, Bladder stones, obese, hiatus hernia, CHF, hyperaflexia syndrome	Lift only, Completely immobile	28	58	Contisol G
2	Female	Metastatic breast cancer	Spinal cord compression, diabetes, anxiety disorder, osteoarthritis, psoriasis	2-person transfer to w/c	30	65	Saline
3	Female	Diabetic	Obese, TIA, hard of hearing, depression, CHF, sacral ulcers, DVT and PE	Lift, bedridden 4 person to transfer or turn in bed	25	76	Control
4	Male	Metastatic prostate cancer	Atrial fib, paralysis, Depression, MI, hearing deficit, urinary retention				
5	Male	CHF	Diabetic	2-person assist/w/c	28	78	Control
6	Female	COPD	Aortic stenosis, mild dementia, CHF, MRSA Positive	2-person assist, uses w/c	Refused to complete	90	Control
7	Female	MS	Depression, bipolar, history of spasms	2-person transfer, w/c	25	31	Control
8	Female	Rt sided hemi-paresis	Atrial fib COPD, Osteoporosis, TIA, aphasia, CVA	2-person transfer	Unable to obtain due to aphasia	83	Control
9	Male	Adenocarcinoma of salivary gland	COPD, CHF ischemic heart disease, atrial fib	1-person transfer	26	80	Saline

Dipstick Urinalysis

Urine pH Levels. Urine pH was documented at baseline (day 0) and weekly thereafter for all three groups. The pH levels on day 0 of all subjects ranged from 5 to 7.5. For the single subject randomized to the Contisol G, pre-irrigation urine pH ranged from 6 to 8.5; 10 minutes post-Contisol G irrigation urine pH was 5.0. In the saline intervention group pre-irrigation, the pH level of the urine ranged from 5 to 7.5; 10

minutes post-saline irrigation, the pH ranged from 5 to 7. In the control group, the pH ranged from 5 to 8.5. These results were consistent over the study period.

Urine leukocyte, nitrite, and haemoglobin levels. All urinalyses were within normal limits for catheterized patients. On day 0 the leukocyte levels of the urine ranged from negative to moderate, and the nitrite levels were negative. Throughout the study, for all three groups, the leukocyte levels ranged from negative to large amounts, and the nitrite levels ranged from negative to positive. Haemoglobin in the urine ranged from negative to largely hemolyzed on day 0 of the study. In the Contisol G group, haemoglobin (pre-irrigation) ranged from negative to trace amounts; in the saline group it ranged from negative to large amounts; and in the control group, the haemoglobin ranged from trace non-hemolyzed to large amounts of hemolyzed haemoglobin. In summary, the urine pH, leukocyte, and microscopic haemoglobin results ranged widely within and between subjects and were within normal limits, for people with long-term IUC (Table 2).

Table 2

Urine Testing Results from Reagent Strips

Contisol G Irrigation: pH, Leukocyte, Haemoglobin, and Nitrite Levels

Subject n = 1	Week	pH		Leukocytes	Hg	Nitrites
Subject #1	Day 0	5.0		Moderate	Large	Negative
		Pre	Post			
	Week 1	6.0	5.0	Negative	Negative	Negative
	Week 2	8.5	5.0	Small	Trace	Negative
	Week 3	8.5	5.0	Large	Negative	Negative
Study endpoint met; catheter changed three times.	Week 4					
	Week 5					
	Week 6					
	Week 7					
	Week 8					

(table continues)

Saline Irrigation: pH, Leukocyte, Haemoglobin and Nitrite Levels

Subject n = 3	Week	pH		Leukocytes	Hg	Nitrites
Subject #2	Day 0	6.0		Negative	Large	Negative
		Pre	Post			
	Week 1	6.0	6.0	Moderate	Large	Positive
	Week 2	5.0	5.0	Small	Trace	Positive
	Week 3	5.0	5.0	Small	Trace	Positive
	Week 4	7.0	6.5	Moderate	Moderate	Positive
	Week 5	7.5	6.5	Moderate	Moderate	Positive
	Week 6	6.0	5.0	Moderate	Moderate	Positive
	Week 7	5.0	5.0	Small	Negative	Negative
(No irrigation)	Week 8	5.0		Small	Negative	Negative
Subject #4	Day 0	6.0		Moderate	Large	Negative
		Pre	Post			
	Week 1	7.5	6.5	Moderate	Large	Negative
	Week 2	7.5	7.0	Large	Moderate	Positive
	Week 3	7.0	5.0	Moderate	Moderate	Positive
	Week 4	5.0	5.0	Moderate	Moderate	Positive
	Week 5	6.5	6.5	Small	Moderate	Positive
	Week 6	6.5	6.5	Moderate	Negative	Positive
	Week 7	6.5	6.5	Moderate	Moderate	Positive
(No irrigation)	Week 8	6.0		Moderate	Large	Positive
Subject #9	Day 0	5.0		Trace	Large	Negative
		Pre	Post			
	Week 1	5.0	5.0	Negative	Trace	Negative
End point: subject deceased.	Week 2					

(table continues)

Control Group: pH, Leukocyte, Haemoglobin and Nitrite Levels

Subject n = 3	Week	pH	Leukocytes	Hg	Nitrites
Subject #3	Day 0	6.0	Moderate	Large	Negative
	Week 1	7.0	Small	Negative	Negative
	Week 2	7.5	Moderate	Negative	Negative
	Week 3	7.5	Large	Moderate	Negative
	Week 4	7.0	Moderate	Negative	Negative
	Week 5	7.5	Moderate	Negative	Negative
	Week 6	6.0	Moderate	Small	Negative
	Week 7	5.0	Moderate	Negative	Positive
	Week 8	6.0	Trace	Large	Negative
Subject #4	Day 0	5.0	Moderate	Trace	Negative
	Week 1	6.0	Small	Moderate	Negative
	Week 2	7.0	Negative	Negative	Negative
Catheter changed 3 times					
Subject #5	Day 0	5.0	Moderate	Trace	Negative
Subject withdrew on day 0					
Subject #7	Day 0	7.5	Moderate	Small	Negative
	Week 1	7.0	Moderate	Moderate	Positive
	Week 2	8.5	Moderate	Trace	Positive
	Week 3	7.0	Moderate	Moderate	Positive
	Week 4	6.0	Moderate	Large	Positive
	Week 5	6.5	Moderate	Moderate	Negative
	Week 6	6.0	Moderate	Trace	Positive
	Week 7	6.5	Moderate	Negative	Positive
	Week 8	6.5	Moderate	Negative	Positive
Subject #8	Day 0	7.5	Moderate	Large	Negative
	Week 1	6.5	Moderate	Trace	Positive
	Week 2	7.0	Moderate	Large	Negative
	Week 3	6.5	Moderate	Trace	Negative
	Week 4	6.0	Moderate	Trace	Negative
	Week 5	6.5	Moderate	Trace	Positive
	Week 6	5.0	Moderate	Moderate	Negative
	Week 7	6.5	Moderate	Trace	Positive
	Week 8	6.5	Moderate	Trace	Positive

Incidence of Catheter Encrustations and Blockages

In the first two weeks after insertion of the urinary catheter, no sediment was observed in the catheter or in the urine drainage bag (Table 3). By week 3 all of the catheters, the drainage tubing, and/or the drainage bag had sediment. The amount of visible sediment varied from week to week, but the urine consistently appeared to flow freely through the catheter drainage tubing into the catheter bag. At no point were encrustations palpated in the catheter or visible in the tubing.

Table 3

Catheter Changes and Catheter Blockages

Subject	Group	# catheter changes during study	Reasons for catheter change	Length of time between catheter changes	Visual description of exterior of catheter	Completion of 8-Week study
1	Contisol G	3	Blocked & bypassing X 3	3 days	No visual encrustations	
2	Saline	1	BM	14 days	No visual encrustations noted	Completed study – 8 weeks
4	Saline	1	Bypassing X 1	7 days	No visual encrustations noted	
9	Saline	0		Deceased week 2 of study	No visual encrustations noted	
3	Control	1	BM & bypassing	14 days	No visual encrustations noted	Completed study – 8 weeks
6	Control	3	Bypassing X 2 Ruptured Balloon X 1	5 days	No visual encrustations noted	
7	Control	0		No changes required	No visual encrustations noted	Completed study – 8 weeks
8	Control	0		No changes required	No visual encrustations noted	Completed study – 8 weeks

Reasons for Catheter Changes

During the data-collection period there were a total of nine catheter changes. In the saline group the staff's documented or verbal explanations for the required catheter changes included the pressure of a bowel movement, which caused the catheter to be expelled with an intact balloon (subject 2), and the bypassing of urine (subject 4).

In the Contisol G group (subject 1) the catheter was changed three times because the catheter completely blocked, which resulted in no urine draining into the catheter bag (Table 3). This subject in the Contisol G group experienced autonomic dysreflexia with diaphoresis and severe headaches whenever a blockage occurred and at the time of these symptoms requested that staff check his catheter for signs of blockage.

In the control group the reasons for catheter changes included constipation (subject 3), the catheter balloon becoming deflated and the catheter falling out (subject 6), and the bypassing of urine (subjects 3 and 6).

Incidence of Symptomatic UTIs

There were no observed or documented symptomatic UTIs during the study period.

Reported Level of Comfort

Catheter surveillance: Day 0. On day 0 (insertion of a new catheter) all subjects completed the Catheter Surveillance Questionnaire (Appendix G) to guage their comfort level with a catheter change. Seven of the eight subjects agreed to answer the questionnaires. The eighth subject was aphasic, paraplegic, and unable to write with either hand and thus experienced significant difficulty in responding to the questions either orally or in writing. She preferred not to answer subsequent comfort questions but wanted to continue in the study otherwise. Instead, she agreed to nod her head for *yes* and to turn her head from side to side for *no* when asked about catheter comfort.

Question 1, "Comfort before catheter change," was rated *acceptable* by 6 subjects (75%) and *unacceptable* by 2 subjects (25%). Question 2, "Comfort with catheter insertion," question 3, "Comfort after the catheter had been in place for 15 minutes," question 4, "Comfort 2 hours after the catheter had been changed," and question 5, "Satisfaction with current catheter program" were all ranked as *acceptable* by 7 of the 7 subjects (100%) who completed the questionnaire. The two subjects who rated question 1 *unacceptable* did so because their catheters had not been draining any urine, which resulted in some bypassing, general discomfort, and spasms and required changing. Table 4 summarizes the individual response rates to each of the five questions when the researcher inserted a new catheter over the eight weeks of the study period.

In summary, all subjects rated their catheters as *comfortable* except for two whose catheters had become blocked. In both situations there was no urine output in the catheter, the urine was bypassing, and discomfort was reported because of the catheter blockage.

Contisol G Group: Catheter Irrigation Questionnaire

Each week the subject in the Contisol G group completed the Catheter Irrigation Questionnaire (Appendix H) to measure his level of comfort with the irrigation intervention. Question 1, "Comfort before irrigation," question 2, "Comfort when the solution was felt in the bladder," question 3, "Comfort 15 minutes after having the solution in the bladder," question 4, "Comfort 2 hours after the solution was in the bladder," and question 5, "Satisfaction with current catheter program," were all rated

Table 4

Catheter Surveillance Questionnaire Results

Questions	Groups			
How would you rate your bladder comfort:	Day 0 Normal saline group N = 3		Day 0 Contisol G group N = 1	
Week 1	Acceptable	Unacceptable	Acceptable	Unacceptable
Q.1 Before catheter change?	1	2	1	
Q.2 Comfort when the catheter was inserted?	3		1	
Q.3 Comfort after catheter was in place for 15 minutes?	3		1	
Q.4 Comfort 2 hours after the catheter had been changed?	3		1	
Q.5 How satisfied are you with your current catheter program?	3		1	

How would you rate your bladder comfort:	Day 0 Control group N=4		Week 8 Control group N=3	
Week 2	Acceptable	Unacceptable	Acceptable	Unacceptable
Q.1 Before catheter change?	4		3	
Q.2 Comfort when the catheter was inserted?	4		3	
Q.3 Comfort after catheter was in place for 15 minutes?	4		3	
Q.4 Comfort 2 hours after the catheter had been changed?	4		3	
Q.5 How satisfied are you with your current catheter program?	4		3	

How would you rate your bladder comfort:	Week 8 Normal saline group N = 2		Week 8 Contisol G group N = 0(excluded at week 4)	
Week 3	Acceptable	Unacceptable	Acceptable	Unacceptable
Q.1 Before catheter change?	2			
Q.2 Comfort when the catheter was inserted?	2			
Q.3 Comfort after catheter was in place for 15 minutes?	2			
Q.4 Comfort 2 hours after the catheter had been changed?	2			
Q.5 How satisfied are you with your current catheter program?	2			

Normal saline: N=3 (two subjects made the eight weeks and one deceased prior)
Contisol G: N=1 (subject did not make eight weeks)
Control Group: N=4 (one subject had difficulty in completing the questionnaire and the questionnaire was discontinued on day 0).

acceptable; and question 6, "Would you recommend bladder irrigation?" was answered *yes* (Table 5). Of note is that this subject had a cervical spine fracture with quadriplegia, he had no pelvic or bladder sensation, and he was unable to recognize pain or discomfort during the irrigation procedure. He did, however, experience autonomic dysreflexia symptoms whenever his catheter became blocked. The types of responses documented in his chart when his catheter became occluded included profuse sweating, facial flushing, and an elevated temperature. None of these symptoms occurred during or two hours after the irrigation procedure during the study period.

Saline Group: Catheter Irrigation Questionnaire

Each week the three subjects in the saline irrigation group completed the Catheter Irrigation Questionnaire. Question 1, "Comfort before irrigation," question 2, "Comfort when the solution was felt in the bladder," question 3, "Comfort 15 minutes after having the solution in the bladder," question 4, "Comfort 2 hours after the solution was in the bladder," and question 5, "Satisfaction with current catheter program" were all rated *acceptable*; and question 6, "Would you recommend bladder irrigation?" was answered *yes* (Table 5). Of note, two of the subjects in this group were paraplegic, had no sensation in the bladder and pelvic area, and were unable to sense pain or discomfort with the procedure. Both indicated no sensation in the bladder area; however, they consistently reported their comfort level during the procedure as *acceptable*. Although none of the subjects reported pain during or following the saline irrigation, one experienced slight discomfort on two occasions. This discomfort was located once in the lower quadrant of his abdomen and once in the top anterior part of his thigh at the time of the irrigation.

Table 5

Catheter Irrigation Questionnaire Results

Questions	Groups			
How would you rate your bladder comfort:	Normal saline group N = 3		Contisol G group N = 1	
Week 1	Acceptable	Unacceptable	Acceptable	Unacceptable
Q.1 Before irrigation?	3		1	
Q.2 When solution was felt in bladder?	3		1	
Q.3 15 minutes after having solution in bladder?	3		1	
Q.4 2 hours after solution in bladder?	3		1	
Q.5 How satisfied are you with your current catheter program?	3		1	
Q.6 Would you recommend bladder irrigation?	Yes		Yes	
How would you rate your bladder comfort:	Normal saline group		Contisol G group	
Week 2	Acceptable	Unacceptable	Acceptable	Unacceptable
Q.1 Before irrigation?	3		1	
Q.2 When solution was felt in bladder?	3		1	
Q.3 15 minutes after having solution in bladder?	3		1	
Q.4 2 hours after solution in bladder?	3		1	
Q.5 How satisfied are you with your current catheter program?	3		1	
Q.6 Would you recommend bladder irrigation?	Yes		Yes	
How would you rate your bladder comfort:	Normal saline group N = 2		Contisol G group N = 1	
Week 3	Acceptable	Unacceptable	Acceptable	Unacceptable
Q.1 Before irrigation?	2		1	
Q.2 When solution was felt in bladder?	2		1	
Q.3 15 minutes after having solution in bladder?	2		1	
Q.4 2 hours after solution in bladder?	2		1	
Q.5 How satisfied are you with your current catheter program?	2		1	
Q.6 Would you recommend bladder irrigation?	Yes		Yes	

Questions	Groups			
How would you rate your bladder comfort:	Normal saline group N = 2		Contisol G group N = 0	
Week 4	Acceptable	Unacceptable	Acceptable	Unacceptable
Q.1 Before irrigation?	2			
Q.2 When solution was felt in bladder?	2			
Q.3 15 minutes after having solution in bladder?	2			
Q.4 2 hours after solution in bladder?	2			
Q.5 How satisfied are you with your current catheter program?	2			
Q.6 Would you recommend bladder irrigation?	Yes			
How would you rate your bladder comfort:	Normal saline group		Contisol G group	
Week 5	Acceptable	Unacceptable	Acceptable	Unacceptable
Q.1 Before irrigation?	2			
Q.2 When solution was felt in bladder?	2			
Q.3 15 minutes after having solution in bladder?	2			
Q.4 2 hours after solution in bladder?	2			
Q.5 How satisfied are you with your current catheter program?	2			
Q.6 Would you recommend bladder irrigation?	Yes			
How would you rate your bladder comfort:	Normal saline group		Contisol G group	
Week 6	Acceptable	Unacceptable	Acceptable	Unacceptable
Q.1 Before irrigation?	2			
Q.2 When solution was felt in bladder?	2			
Q.3 15 minutes after having solution in bladder?	2			
Q.4 2 hours after solution in bladder?	2			
Q.5 How satisfied are you with your current catheter program?	2			
Q.6 Would you recommend bladder irrigation?	Yes			

Questions	Groups			
How would you rate your bladder comfort:	Normal saline group		Contisol G group	
Week 7	Acceptable	Unacceptable	Acceptable	Unacceptable
Q.1 Before irrigation?	2			
Q.2 When solution was felt in bladder?	2			
Q.3 15 minutes after having solution in bladder?	2			
Q.4 2 hours after solution in bladder?	2			
Q.5 How satisfied are you with your current catheter program?	2			
Q.6 Would you recommend bladder irrigation?	Yes			
How would you rate your bladder comfort:	Normal saline group		Contisol G group	
Week 8	Acceptable	Unacceptable	Acceptable	Unacceptable
Q.1 Before irrigation?	2			
Q.2 When solution was felt in bladder?	2			
Q.3 15 minutes after having solution in bladder?	2			
Q.4 2 hours after solution in bladder?	2			
Q.5 How satisfied are you with your current catheter program?	2			
Q.6 Would you recommend bladder irrigation?	Yes			
How would you rate your bladder comfort:	Normal saline group		Contisol G group	
	Acceptable	Unacceptable	Acceptable	Unacceptable
Q.1 Before irrigation?	2			
Q.2 When solution was felt in bladder?	2			
Q.3 15 minutes after having solution in bladder?	2			
Q.4 2 hours after solution in bladder?	2			
Q.5 How satisfied are you with your current catheter program?	2			
Q.6 Would you recommend bladder irrigation?	Yes			

In summary, the subjects in both the Contisol G and saline groups rated their comfort level before the irrigation and following the irrigation as *acceptable* during the study period. All the subjects rated their current catheter programs as *acceptable*, and all the subjects (100%) indicated that they would recommend bladder irrigations as an acceptable procedure.

Direct Cost of Equipment and Nursing Time

No Irrigation/Standard Practice

The average time for a standard catheter change, including teaching (explaining the catheter insertion procedure), setting up supplies for carrying out the procedure, inserting the catheter, and cleaning up, was approximately 45 minutes (Table 6). The estimate did not include documentation post-procedure. The average wage for a registered nurse (RN) at the time of the study was $35.60 per hour, and for a licensed practical nurse (LPN), $19.94 per hour. The cost for an RN to insert a catheter was $26.70 ($35.60 x 45 minutes). The approximate cost of the supplies for insertion of a catheter (excluding pH testing, which is not part of routine IUC care) was approximately $11.00. The total costs of supplies and for an RN to set up the catheter insertion tray and insert a catheter was approximately $37.70 ($26.70 + $11.00) once per week, or $150.80 per one month (four catheters in four weeks). The cost for an LPN was $14.96 ($19.94 x 45 minutes); with supplies, the cost was $25.96 ($14.96 + $11.00) per one week, or $103.84 per month (four catheters in four weeks).

In three situations the catheterization procedure exceeded 60 minutes because of a number of variables unique to the individual. One subject was morbidly obese and had limited hip mobility; thus the procedure took extra time. In this case it routinely took four

Table 6

Nursing Time and Supply Costs

	RN cost per hour	LPN cost per hour	Irrigation supply costs	Changing catheter supplies	Minutes to complete procedure	Total nursing costs and procedure costs per week	Total nursing costs and procedure costs per month
Saline or Contisol G Irrigation by RN	$35.60 ($8.90)		$3.50		15 min	$12.40	$49.60
Saline or Contisol G Irrigation by LPN		$19.94 ($4.99)	$3.50		15 min	$8.49	$33.96
Standard catheter change by RN	$35.60 ($26.70)			$11.00	45 min	$37.70	$150.80
Standard catheter change by LPN		$19.94 ($14.95)		$11.00	45 min	$25.95	$103.80

staff members to help with the insertion of the catheter because of the physical challenges of inserting the catheter into this person. In also took an additional 30 minutes to find extra staff to assist with the procedure and one hour to insert the catheter. In another subject it was difficult to insert the catheter because of the combination of lack of mobility, obesity, and the anatomy of his penis. Because of a urethral stricture in the third individual, the procedure required additional time as well.

Irrigation With Contisol G or Saline

The average time to complete the irrigation with Contisol G or saline was 15 minutes, including the pH testing. The cost for an RN was $8.90 ($35.60 RN salary x 15 minutes) and for an LPN, $4.99 ($19.94 LPN salary x 15 minutes). The cost of supplies for Contisol G irrigations or saline irrigations, including testing the urine with a reagent strip, was approximately $3.50 per one week (sterile prepackaged irrigation solution, either Contisol G or saline; disposable gloves; alcohol swab), or $14.00 per month (once a week x four weeks). The cost for an RN to set up supplies and irrigate the catheter with saline or Contisol G (including the urine pH testing) was $12.40 ($8.90 RN nursing time costs and $3.50 supplies) per week, or $49.60 per month, including supplies. The cost for an LPN was $8.49 ($4.99 LPN nursing time costs and $3.50 supplies) per week, or $33.96 per month.

If irrigation with Contisol G or saline is effective, the costs for the irrigation procedure are less than the costs to insert an IUC (Table 6).

Summary of Results

The first objective of this pilot was to examine the various strategies used for resident recruitment. Although a number of the strategies (inservices, posters, Internet, and e-mail) may have contributed to improved awareness about the study, the researcher's weekly visits to the unit appeared to be the most effective method of recruiting subjects in this particular setting. The second objective was to test the procedures used to compare the Contisol G or saline irrigation subjects to the standard care group over eight weeks, and the descriptive statistics were effective in capturing the frequency of catheter blockages, the urine characteristics (urine pH, leukocytes, haemoglobin, and nitrite levels), and the direct costs of nursing time and supplies. The combination of nonexistent or fragmented documentation on the subject's catheter, the limited documentation of any type of catheter plan, and the lack of standardization of catheter care in this setting made it very difficult to control for other variables that contribute to IUC blockages aside from encrustations. In addition, the tools used to measure comfort and to screen for cognitive alertness had a number of limitations because of the functional disabilities of a number of the subjects. No adverse events were noted in this study. Moreover, three of the subjects (two in the saline group and one in the Contisol G group) reported that they enjoyed participating in this research study and requested to be re-enrolled if there was another phase of the study.

CHAPTER 5:

DISCUSSION

An interpretation of the results of the pilot study with support from the current literature and the implications of the results for the larger study are presented in chapter 5. The evaluations of the procedures for resident recruitment are discussed first. This is followed by a discussion of the results of pilot testing procedures for comparing the subjects assigned to one of the three catheter management groups (irrigations with Contisol G, normal saline or standard practice) during an eight week period. Other unexpected topics that arose in the course of conducting the pilot study are then discussed. Finally, the limitations and conclusions are presented.

Resident Recruitment

The key findings from the evaluation of the procedures for resident recruitment pertained to the sampling technique and to gaining entry and soliciting study support. Each is discussed below.

Sampling Technique

Of the inclusion criteria for subject selection, "a history of blockage problems" was difficult to apply. A lack of nursing documentation on catheter care and the problems encountered was a major challenge in determining the history associated with catheter blockages or bypassing. Consequently, it was difficult to establish from the documentation in the residents' charts or from the nursing staff whether the subjects experienced blockages and/or bypassing of urine from encrustations or other possible causes. Getliffe (1994) discussed the range of causes of blockages, such as constipation, catheter twisting, bladder spasms, large diameter catheters, large catheter balloons, under inflated catheter balloons, and encrustations. Based on this finding, it is recommended that the larger study track the potential subjects' catheter history, insertion pattern, changes, and IUC care systematically for a two-month period prior to starting the study to determine whether they have a history of blockages caused by encrustations.

Screening MMSE

In an effort to ensure that the subjects were competent to consent to participate in this study and were not cognitively impaired, the MMSE was selected as a practical, validated, and reliable generic screening tool. The MMSE cut-point score for inclusion (≥ 23) helped to ensure that the subjects recruited were competent to decide whether they wanted to participate and to ensure that they were not cognitively impaired. Although a score ≥ 23 is considered normal, actual performance varies with the age and education of the individual (Molloy, Standish, & Lewis, 2005; Santacruz & Swagerty, 2001; Crum, Anthony, Bassett, et al, 1993). The MMSE is a widely studied instrument that has been identified in the literature as a valid and reliable bedside test for an initial screening assessment and for serial measurements to identify deterioration or improvements over time and with treatment; however the original authors also noted that the MMSE does not replace a complete clinical appraisal (Folstein, Folstein, & McHugh, 1975).

The literature suggested that using an arbitrary cut-off point such as that used in this study (≥ 23) may potentially lead to more false positives among older people with lower education levels and increase the false negatives for younger people with more advanced educational levels (Molloy et al., 2005). Tombaugh and McIntyre (1992) also recognized the MMSE as a valid screening tool but recommended that it not be used in isolation or as a single diagnostic tool for determining dementia.

Researchers such as Ferrucci et al. (1998) found that the MMSE is not suitable for persons with severe visual or upper extremity impairments. Residents in long-term care facilities have numerous co-morbidities that affect their ability to use upper-arm fine movements and to respond to questions verbally. In this catheter study four of the subjects had difficulty completing the MMSE. One subject, a quadriplegic, had to use his mouth to draw the pentagon. Another with aphasia was unable to express herself verbally or use her arms because of a stroke. She was able to respond with some head movements and short word responses but she became frustrated with her inability to communicate the standard responses to the MMSE questions. A third subject experienced difficulty in reading and writing because of the rapid onset of her neurological disease. Although the documentation in the chart and clinicians considered her as cognitively alert and competent, she was not able to complete the MMSE. The fourth subject found the MMSE a burden and refused to do it. The staff and subjects' families felt that each of these subjects were cognitively competent to consent and to participate in a research study.

Although the MMSE is an effective bedside screening tool for cognitive impairment and/or cognitive changes, it did have some limitations in screening subjects for this study. Some of the MMSE's limitations are the use of an arbitrary score, education and age factors, the burden to the individual, visual impairment, and limited fine motor movements. It is recommended that the version of the MMSE that includes education in the scoring component be adopted and that MMSE and/or clinical judgment be added to the inclusion criteria to determine whether a resident is competent to participate in a study.

Gaining Entry and Promoting Study Support

Recruiting appropriate subjects with indwelling catheters with a history of blockages in a long-term care facility was difficult because of the high levels of dementia, language barriers, the frequent symptoms of UTIs, the limited number of residents with indwelling catheters, and residents' and staff's perceived burden of being involved in a research study. The staff and managers commented that they were so busy that they would forget to call when a potential subject was identified on the unit.

Several strategies were combined in an effort to promote the visibility of the study and to improve recruitment. Establishing a clear enrolment start and end date made the recruitment process more visible to interested staff and residents. One-on-one visits by the student researcher to the units were found to be the most effective means of recruiting subjects in this setting with 16 of the 18 residents identified as potential subjects by the direct visits. Only two of the 18 were identified through other recruitment strategies.

Recruitment strategies included an Internet advertisement; a brief paragraph in the local residents' newsletter promoting the study; an information sheet for residents and one for staff; letters to the medical director, the director of continuing care, and the managers; colour posters promoting the study on every unit and on the doors of each nursing unit; one-on–one sessions (in which the student researcher went to each unit, reviewed the study criteria with the nurse in charge, and asked permission to meet with potential subjects on that particular unit); and staff inservices. Despite this effort, the three-month collection period resulted in only one phone call and two e-mails from staff to identify potential subjects. Formal published evaluations of effective strategies for recruitment for clinical studies in community settings compared to hospital settings are limited (Silagy et al., 1991). The study setting was multicultural with some interpreters, so that including non–English-speaking subjects (based on interpreter availability) would have imporved opportunities for ethnic and minority populations to become involved and increased the number of potential subjects.

Comparing Subjects Assigned to One of the Three Catheter Management Groups

Using inferential statistics to make group comparisons was deemed inappropriate given the small sample size. The following sections include a discussion of the results of group comparisons using descriptive statistics. The outcome variables include the dipstick urinalysis (urine pH, leukocytes, nitrites, and haemoglobin levels), the frequency of visible encrustations, visible catheter blockages, the reasons for catheter changes, the symptomatic UTIs, comparisons among the three groups of the comfort levels, the direct costs of medical supplies and nursing time, and other issues.

Dipstick Urinalysis, Urine pH Levels

Urinalysis reagent strips were used to test the urine pH over the eight-week period. The pH level of subjects ranged between 5 and 8.5 in all three arms throughout the eight weeks. There were no significant changes in the pH level after irrigating with Contisol G or saline. The pH levels in all of the subjects fluctuated from week to week regardless of which intervention they received. Getliffe (2004) found that the pH level of urine in patients with a history of blockages ranged from 7.5 to 9.5. Other researchers such as Burr and Nuseibeh (1997) and Hedelin et al. (1991) have also found that individuals with a blocking tendency have elevated pH levels or alkaline urine. Choong, Wood, Fry, et al. (2001), Kohler-Ockmore and Feneley (1996), and Getliffe (1994) found that non-blockers have more acidic urine (pH 6.5) than do patients who block (pH 7.5 or greater). Mathur, Suller, Stickler, and Feneley (2006) followed 20 catheterized patients for 12 weeks and found that the pH of their urine also fluctuated week to week. The variation suggests that there may be a way to alter this value and potentially reduce the rate of encrustation build-up.

Dipstick Urinalysis, Urine Leukocytes, Nitrite and Haemoglobin Levels

Almost all of the subjects tested positive for leukocytes in their routine weekly assessments following day 0. The number of leukocytes fluctuated from week to week, and none of the subjects developed symptomatic bacteria during the study. Muncie, Hoopes, Damron, Tenney, and Warren (1989) showed that bacteria will be prevalent in catheter urine regardless of the type of intervention. Elliot et al. (1989) are among many researchers who have reported that leukocytes do not change following a catheter irrigation; therefore, there is no rationale for testing urine for leukocytes post-irrigation.

Urine that tests positive for nitrites is one indicator of UTIs in non-catheterized patients if the urine remains in the bladder for several hours to allow the conversion of nitrites to nitrates by gram negative organisms. An interesting observation in this study was that four catheter urine samples tested positive for nitrites. Typically, free-flowing urine in the catheters does not remain in the bladder for several hours and thus should test negative for nitrites. A standard nursing protocol in this study setting was to perform a UTI investigation on residents whose urine tested positive for both leukocytes and nitrites. The microbiology, culture, and sensitivity test results confirmed that none of these subjects had symptomatic UTIs and consequently did not require antibiotic therapy.

Urine was tested weekly for haemoglobin prior to any intervention and in almost all cases tested positive. Although the literature suggested that haemoglobin in the urine is another indicator of UTI, the results of this study reveal that microscopic haemoglobinuria and leukocytes appeared frequently and were not predictors of UTIs in this sample. In previous studies saline irrigations or acetic acid irrigations with the standard 60-cc syringe, were found to increase haemoglobin in the urine samples (Kennedy, Brocklehurst, Robinson, & Faragher, 1992). It is recommended that in the larger study, post-irrigation, the urine be tested for haemoglobin in addition to measuring the pH. This comparison would provide some data on whether this new, gentle irrigation process results in haemoglobin changes in the urine sample.

Visual Description of Catheter Encrustations and Frequency of Blockages

Throughout the duration of the pilot study no visible or palpable encrustations were noted in any of the subjects' catheters. Getliffe (1994) suggested slicing the catheter in half and inspecting it internally to observe encrustations. In eight situations the subjects' catheters required changing because of blockages, the absence of urine flow, and/or the bypassing of urine around the catheter. In two of these situations the subject was oozing stool and may have been constipated, another factor to urine bypassing the catheter. In the larger study, slicing the catheter post-removal is recommended to confirm that the catheter blockage was actually caused by encrustations.

Reasons for Catheter Changes

The small sample size resulted in insufficient data to determine whether there was any difference among the three groups in the life of the catheter. Although the sample was too small to make generalizations or draw conclusions, the staff anecdotally commented on the subjects in the saline irrigation group: "Whatever the student researcher was doing worked. The catheter was finally lasting longer"; and "Whatever you are putting into that catheter is working, and we have not had one problem with that catheter since the study started." However, due to the pragmatic changes in catheter care as a result of the study catheter type, the smaller balloon, appropriate type and amount of solution in the balloon, regular assessment, and anchoring of the catheter, it is not clear whether the irrigation or improved practices contributed to a reduction in the blockages in these isolated situations.

In the Contisol G arm, the subject's catheter blocked daily so required saline irrigations every day prior to enrolment. Each time his catheter blocked, a nurse would irrigate his catheter. During study participation he received irrigations once a week (compared to daily) with the prepackaged 50 mls of Contisol G. His catheter blocked three days following each Contisol G irrigation, so his catheter life extended from one day to three days. It is possible that the subject would benefit from twice weekly or sequential irrigations. Getliffe, Hughes and LeClaire (2000) showed in the laboratory that sequential irrigations were more effective than a single irrigation.

Rew and Woodward (2001) and Gray (2004) found that the balloon and catheter size, the composition of the catheter, and constipation could increase the incidence of bypassing and blockage problems. Offering each subject individualized teaching on catheter care may have had an indirect effect on the reduction in complications such as bypassing. For example, after being in the study for one week, one of the subjects insisted that staff anchor his catheter to his leg and empty the bag more frequently. In the past the staff had not been anchoring the catheter to his bag and had emptied the bag twice a day regardless of how full it was. Smith (2003), Rew and Woodward (2001), and Getliffe (2003) all recommend that patient education become a component of the practice guidelines in routine catheter care.

Incidence of Symptomatic UTIs

Symptomatic catheter-related infections are the most common infections in continuing care settings (Classen, Larsen, Burke, & Stevens, 1991). These infections are often caused by pathogens that are multidrug resistant (Maki & Tambyah, 2001). None of the eight subjects developed a symptomatic UTI during the eight-week data-collection period. In the three cases in which the residents' urine tested positive for leukocytes and nitrites there were no other observed or documented symptoms of a UTI and the microbiology, culture, and sensitivity urine tests were reported to the student researcher as being negative.

Catheter Comfort Descriptors

Overall, the subjects in the present study rated their catheter comfort *acceptable* 90% of the time. Only two subjects rated their catheters as *unacceptable*, and in both situations their catheters had become blocked and were bypassing urine. Although the sample is too small to draw any conclusions, the data supported the work of Roe and Brocklehurst (1987) and Wilde (2002), who suggested that patients' satisfaction with catheters is good until complications arise. The subjects in the Contisol G arm and saline arm rated their comfort with the irrigations *acceptable* 100% of the time prior to the irrigation, 15 minutes post-irrigation, and two hours later. The irrigation procedure did not cause any adverse problems or discomfort for any of the subjects. It is important to note that one subject experienced a burning sensation with the irrigation procedure, but still rated his comfort *acceptable*; he did not consider the burning a form of pain or discomfort. It is also interesting to note that five of the eight subjects who responded to the comfort questions had some form of paralysis that affected their ability to feel their catheters or the irrigation procedure. Although there is a growing amount of research on long-term catheters, there is limited research on residents' perspectives of their experience with catheters. Wilde (2002), Getliffe (1990), and Brennan and Evans (2001) suggested that blockages in catheters cause pain and distress for patients. Roe and Brocklehurst (1987) identified discomfort in 75% of 36 catheterized patients. Of this group, 30% had experienced catheter related pain. In Wilde's study, 10 of the 14 subjects complained of catheter pain. Autonomic dysreflexia caused pain for four of 14 of the subjects in Wilde's (2002) study. Others described the catheter as annoying and cumbersome, particularly when they were sitting and the catheter was not positioned correctly. Most of the subjects found catheters problematic when they did not work properly and described the experience as frustrating and as making them feel dependent or vulnerable.

Limitations of Assessment Measurement Tools

The two questionnaires used for assessing bladder comfort in this study were the Catheter Surveillance Questionnaire (Appendix C) and the Catheter Irrigation Questionnaire (Appendix D).

Catheter Surveillance Questionnaire (Appendix C)

A number of limitations were noted with the Catheter Surveillance Questionnaire. Four subjects had some degree of paraplegia and could not feel their catheters. In all cases their response to the question on catheter comfort was *acceptable* because the questions lacked a *not applicable* response. All eight subjects found the question on "satisfaction with the current catheter program" confusing. The comfort questions focused on bladder sensation and provided room for other comments. There was no opportunity to address the psychosocial burdens of catheters or other autonomic dysreflexia symptoms such as one subject's headaches, flushing, and fever associated with catheter use or another subject's burning sensation in the leg. When the student researcher asked the subjects more specific questions such as "Where is your bladder?" or "What is the current catheter program?" they were unable to articulate a response or would say, "I do not know." Although the questions were tested by expert continence professionals for content validity, they were not pretested with non-healthcare members. Piloting the questions with laypersons could have improved the interrater reliability. Including a diagram to allow the subject to circle or point to the place of pain and a question rating the burden of the catheter experience might also have been helpful. In addition, many of the respondents were unclear about the difference in meanings between words in the responses such as *acceptable* and *good*. The use of a numerical or Likert scale for the comfort scores might have helped to clarify the difference between these two terms, as well as the inclusion of a diagram of the human body to allow the subjects to mark the specific areas in which they experienced discomfort. Adding a question on whether the subject had any sensation in the pelvic area would also be helpful to determine the ability differentiate between *comfort* and *pain*.

Catheter Irrigation Questionnaire (Appendix D)

The catheter irrigation question focused on bladder comfort and did not address any other types of discomfort that could result from the irrigation procedure, such as autonomic dysreflexia. This questionnaire could have been improved by testing the interrater reliability with laypersons as well. Questions were raised regarding the need to check for bladder comfort 15 minutes post-irrigation and two hours post-irrigation and whether one hour post irrigation would have been more practical. The subjects were often not in their rooms or busy with other activities two hours post-procedure.

Medical Supplies and Nursing Time

An irrigation with prepackaged Contisol G or saline cost approximately $ 5.00 to $ 9.00 and took, on average, about 15 minutes. An uncomplicated catheter chage was found to cost approximately $ 15.00- $ 27.00 and took, on average 45 minutes of nursing time. The data from this study suggest that the irrigation process is fairly inexpensive compared to a catheter change. If regularly planned irrigations can extend the life of the catheter by 25%, this intervention could help to reduce the burdens associated with bypassing and blockages, unplanned catheter changes, and the costs of frequent catheter changes. The management of blocked catheters uses extra resources and nursing time (Evans et al., 2001; Getliffe, 1990). Evans estimated the cost of managing a blocked catheter in the home at approximately $55.00 during the day and substantially more during the night shift or on weekends. However, Muncie et al. (1989) suggested that daily irrigations are a costly intervention. In a non-randomized study the author compared 10 weeks of daily saline irrigations to 10 weeks of no irrigations in 32 females, they found no improvement in reducing blockages and concluded that irrigating catheters with saline is time consuming and costly. A major limitation of the above study was the procedure was carried out daily on all catheterized patients, including on those without a history of blocking or problems. Moreover, the conventional method was used of catheter irrigations with a sterile tray and a 60 cc syringe which requires extra time to set up the supplies and carry out the procedure compared to the prepackaged sterile irrigation solutions used in this pilot. Roe (1989) commented that the new prepackaged irrigations solutions might be more economical to use than the conventional irrigation tray. Kennedy, Brocklehurst and Lye (1983) also found the prepackaged solutions easier and more efficient to use than the conventional irrigation trays and proposed that the prepackaged irrigation solutions could be easily taught to patients to use as well.

Other Issues

Conducting research in a nonacademic setting such as a long term care setting poses a unique set of chllenges such as: variations in staff practices in IUC care, staffing shortages, variations in staff skill mix (high percentage of personal care attendants and few professional nurses), lack of familiarity with research protocols, limited documentation on care of the IUC for data collection, limited research uptake and utilization by staff, and the organizational culture. Additional challenges identified in the research protocol included: the back spray from the irrigation product used in the irrigation procedure; the irrigation-product procedure change, the terminology used in educational material; and subject consent form.

Variation in Practices in IUC Care

Although the subjects in this sample were recruited from one facility, the variations in practices in catheter care were significant, based personal preferences rather than the facility's policy or best practices. The documentation on catheter care and insertion varied from staff member to staff member. For example, the reasons for the catheterization and the catheter change, the size and type of catheter, and the balloon size were inconsistently documented or not recorded. Catheter planning was limited to emptying the catheter bag daily. Some of the Kardex care plans did include some relevant IUC information but it was limited to having a latex allergy, the catheter bag emptying routine, or date of the last catheter change. The limited number of catheters in stock on each unit and the variation in the types of catheters used from unit to unit meant that incorrectly sized catheters and balloons were inserted. The procedure for cleaning leg bags also varied between vinegar and water, with soap and water, or rinsing with water. In two situations staff indicated that normal saline was used to fill the catheter balloon even though the manufacturer recommends sterile water. Normal saline can lead to crystal formation in the inflation lumen, inflation with air can cause the balloon to float in the bladder, and/or difficulty deflating the balloon as well as leakage via the balloon membrane (Smith, 2003).

Five of the nine residents had received catheter irrigations with normal saline for blocked IUCs prior to their enrolment in the study. The description of how and why the staff irrigated the catheter varied from unit to unit; some used sterile technique to irrigate, and others used clean technique. Some used 60 ccs of saline in a syringe to irrigate the catheter, and others irrigated with 50 ccs of saline as recommended in the site's policy. Roe (1989) also found that the reasons for irrigating or changing a catheter or the techniques for irrigating a catheter varied significantly among registered nurses.

Although the facility's catheter policy and the catheter-related literature recommend using the smallest catheter (12 French or 14 French) with a small balloon (5 ml), four of the subjects had larger catheters with 30-cc balloons (prior to enrolment to the pilot) placing them at risk for bladder neck destruction. Documentation in four of the subjects' medical charts (prior to their enrolment in the study) indicated that 30 cc balloons and size 18 catheters or larger were inserted because of bypassing of urine. The size of the catheter or the balloon may have caused detrusor instability and further bypassing. Some staff indicated that they would add less fluid to the 30 cc balloon to make it less irritating. They were not aware that the manufacturer recommended complete balloon filling or that there were instructions on the catheter packaging recommending a specific amount of sterile water be inserted into the balloon.

There were also variations amongst the staff in how they changed the catheter bag ranging from changing the bag each time sediment was seen in the catheter drainage bag to changing it if the bag became discoloured or changing it with a catheter change. In one situation the nursing attendant was not familiar with night bags and would disconnect the resident's day leg bag and reuse a non-reusable, contaminated catheter bag every night, even though the manufacturer's instructions indicated that this type of bag is for one-time use only. The catheters in this setting were routinely not secured, a practice standard with which most of the staff approached during the data-collection period were not familiar. Of the 18 potential subjects, only one had his catheter secured to his leg. The staff frequently removed the anchoring device from subjects who were enrolled in the study.

Although the literature identified the importance of emptying the catheter drainage bag before it is three quarters full, on the weekly rounds by the student researcher, most of the subjects' catheter bags were found to be three quarters full or more. This caused additional tension on the catheter and the potential for bladder-neck and urethral trauma as well as impeding urine drainage. The nursing staff reported that nursing attendants emptied the catheter bags once every day. However, although the LPN and RN staff were aware of the importance of emptying catheter bags regularly and before they become full, the practice was not being carried out on their units. The clinical educator was made aware of this practice issue, and she suggested that the student researcher bring it forward to the nursing attendant training program staff. Another example of practice challenges was taking a proper urine specimen from a catheter. Two RN staff reported to the student researcher that they had been taught to take the urine sample from the catheter bag and that they were not familiar with using the port on the catheter tubing to obtain urine samples or using a new catheter to collect the urine specimen. The staff were not aware of the necessity of inserting a new catheter into a resident who is being investigated for a symptomatic UTI or of obtaining a urine sample from the new catheter.

One LPN and an RN informed the student researcher that they order cranberry juice for every catheterized resident with the belief that this would reduce catheter related infections. They were unaware that the evidence is inconclusive to support this practice. In one case the resident disliked cranberry juice and was relieved to learn that he needed only to increase his oral intake and would no longer have to drink a juice he disliked.

The subjects in this study were selected because of a history of catheter blockages and/or bypassing, but it remains unclear whether the blockages were a result of causes other than encrustations. Factors such as constipation, large balloons (30 ccs), the weight of urinary catheter bags that are more than three quarters full of urine, and large catheters can cause bypassing and blockages without any encrustation (Cravens & Zweig, 2000). All of the subjects enrolled in the study were started on day 0 with a standardized hydrophilic catheter with a 5-cc balloon. It is possible that the smaller catheter and balloon may have contributed to reduced problems with bypassing and blockages in the five subjects who completed the study. Bull et al. (1991) compared silicone-coated catheters (silastic) to hydrophilic catheters for blockages in 69 subjects. They found that the hydrophilic catheter remained in situ for an average of 89.61 days compared to 25 days for the silicone catheter. Urine was bypassed in only about 28% of the hydrophilic catheter group compared to 53% of the silicone catheter group. Hence the quality of the catheter may have directly helped to reduce the frequency of catheter-related problems.

Staffing Shortages and Variations in Skill Mix

Although the nursing profession clearly recognizes the importance of research in practice, staff shortages and heavy workloads have been identified as two barriers to the implementation of research findings in practice settings (Newhouse et al., 2005; Retsas, 2000). The casual nursing staff in this long-term care setting were often not familiar with the residents for whom they were caring. For example, on three separate units on the same day the casual/relief LPN who was in charge on each particular unit did not know who had catheters. In another situation the acting manger was aware that one of the exclusion criteria in the catheter study was latex allergy; however, she referred a potential subject to the study who had a latex allergy that had been documented in the Kardex. None of the regular staff approached that day were cognizant of this allergy or of which products had latex in them; consequently, latex products were being stocked in her room. Documentation in the chart showed that staff had inserted a latex catheter into this resident on several occasions. The subject was not aware of having a latex allergy and could not recall ever experiencing any sensitivities or reaction to a latex product or to any previous latex catheters. An assessment of her history revealed that she apparently did not have a true allergy to latex, and she therefore agreed to be enrolled in the study and have a hydrophilic (coated latex) catheter inserted.

The current realities of heavy workloads, clinical priorities, and limited staffing arrangements have a tremendous impact on the staff's ability to find time to learn about evidence-based practices and the best ways to integrate them into their practice. Administrative support is vital in providing resources to promote evidence-based practices by nurses. In this particular setting the high ratio of nonprofessional staff created additional challenges for the nursing staff in incorporating best practices at the bedside. Because reduced staffing and staff shortages are common during the summer months (the data-collection period of this study), data collection should be promoted during the regular season and avoided during peak vacation periods such as the summer months and Christmas.

Lack of Familiarity with Research Protocols

Although the staff and managers were receptive to having research conducted at their site, most were unfamiliar with standard processes that researchers must follow. For example, they did not understand why consent from the resident or agent was required to participate in research, why the consent needed to be witnessed, why the study required some standardization such as similar catheters or smaller balloons, or why dementia was an exclusion criteria. A number of the words used to describe the study were also unfamiliar to the staff, such as *long-term urinary catheter* and *indwelling urinary catheter*. Instead, they used the term *Foley catheter* for any type of indwelling catheter. Words such as *blocked catheter*, *indwelling catheter*, and *irrigation solution* needed frequent explanations. The staff commented, "There were no problems with the Foley, but I do irrigate it with saline whenever a resident bypasses urine"; and "I flush it with saline when I cannot see any urine draining into the bag, but there is no blockage problem"; and "Blockages are rarely a problem because the nursing staff irrigate the catheters with saline." This communication barrier was remedied with words with which the staff were more familiar, such as *Foley catheter* instead of *indwelling urinary catheter* and *bypassing urine* or *no urine output* instead of *blockages* or *encrustations causing blockages*.

Research Uptake and Utilization

Integrating research findings into routine healthcare is a fragmented process (Eccles, Grimshaw, Walker, Johnson, & Pitts, 2005). For research to be integrated into practice, knowledge transfer must be part of the culture (Parahoo, 2000; Rodgers, 2000). Although there are readily available clinical practice guidelines on catheter care, catheter policies supported by evidence and review articles on urinary catheter management, best practices in UIC were not part of the standard practices in this setting, and the staff did not appear to know where to access these resources. They had a range of ideas on catheter management that were often not supported by best practices, although they were eager to learn about ways to improve the catheter care of their residents.

While there is an interest in implementing research findings into practice, there are often many reasons that the findings do not reach practice, such as social, organizational, and institutional barriers or limited research-based information ready for clinical application (Haines & Donald, 1998). Retsas (2000) suggested other barriers, such as lack of skills to carry out the intervention or clinicians who feel that they lack autonomy to make such decisions. Other barriers include a lack of access to research, staffing shortages, and a lack of knowledge and skills to interpret the research findings. These factors may have prevented the nurses in the research setting from integrating current evidence on catheter care.

In this particular setting the nursing staff and management team were receptive to having research conducted on their units and expressed an interest in finding out more about evidenced-based catheter care. The nurses frequently sought expertise from the student researcher on best practices or evidence-based practices on a wide variety of catheter-specific issues during the data-collection period. Examples of topics in which the nurses expressed interest included "why does urine turn purple," "how often should catheter bags be changed," "what is the best way to collect a urine sample," "how is the decision made on type and size of catheter," "can a resident can have sexual intercourse if they have an IUC," "how do we find research articles that support the reuse of an intermittent catheter in long term care," and "how is urinary retention assessed." Rodgers (2000) found that if nurses are not made aware of practice changes or evidence-based practices, they would not be aware of the need to change or improve their practices. Wallin, Bostrom, Wikblad, and Ewald (2003) reported that even though nurses may express an interest in research, most use it sparingly because of the identified barriers. However, as a result of this research project, devices to secure catheters have now been made available to the units, the staff educator has attended a session on improving catheter care, and the site best practice committee is currently developing a best practice document on catheter care.

Organizational Culture

A valuable component of research collection in any clinical area is familiarity with the organizational culture. In this research project the student researcher had the advantage of being familiar with the culture of the organization, the managers, the unit champions, and the unit routines, in addition to the potential barriers to conducting research within this setting. The student researcher attempted to identify a champion on each unit as a key contact for recruiting purposes and for promoting compliance with the study protocol once a subject was enrolled. These individuals were instrumental in finding subjects for the study and in identifying issues or problems that arose during the collection period.

Product Advantages and Disadvantages

The product used for irrigations had both advantages and limitations. It was easy to use, quick to assemble, and easy to discard. The entire procedure, including organizing supplies, warming up the irrigation solution, testing urine pH, and cleaning up, took approximately 15 minutes. To use the product, the catheter system had to be opened weekly, which potentially increased the risk for infection. Whether the subjects were at risk for increased symptomatic UTI is unclear. It is recognized that long-term catheterized patients have persistent but asymptomatic colony counts and none of the subjects in the irrigation arms developed a UTI.

A second problem with the product was the backspray. If there was any resistance or sediment in the catheter lumen, there was a small amount of backspray of urine mixed with the solution from either the prepackaged Contisol G product or saline, which occurred approximately 50% of the irrigation procedures. Developing a two-way valve that could be attached to the catheter for routine irrigation might alleviate both problems of opening the system and irrigation backspray. Finally the Multistix® reagent strips also had some limitations. If the procedure was not carried out carefully according to the manufacturer's directions and extra urine remained on the reagent strip, a false reading could occur. For example, the protein reagent could run into the pH reagent and cause an incorrect low pH value (Bayer Diagnostics, 1999).

Irrigation Procedure Change

During the study two changes occured with the prepackaged Contisol G and saline irrigation solutions. The first was a name change from *Suby G* to *Contisol G*, the second was a recommendation by the manufacturer to discontinue clamping of the catheter for 15 minutes after the irrigation. This second change was based on the laboratory work done by Getliffe, Hughes and LeClaire (2000). Their work suggested that 50 mls of irrigation solution was as effective as 60 mls in reducing blockages and that extended length of contact of the solution does not further reduce encrustation. Thus the comfort survey question that queried comfort 15 minutes after the irrigation procedure was no longer relevant. The revised protocol for the irrigation procedure was substantially shorter and took only approximately one to three minutes. Currently, there are no systematic clinical studies on the most appropriate amount of time that the irrigation solution needs to be in the lumen and/or bladder to reduce the blockage caused by encrustations.

Terminology Used for Educational Material and Consents

A number of residents had difficulty in understanding the words used in the information and consent form (Appendix E). Although these forms were considered to be at a Grade 6 reading level, the student researcher received feedback during the recruitment process from residents, family members, and staff on the wording. The subject or surrogate often circled words with three syllables for further clarification; for example, the residents and families commonly required further clarification on *irrigate*, *irrigation*, and *confidentiality*. The staff were not familiar with some of the terminology, such as *indwelling catheter*, *blockage*, and *hydrophilic catheter*. It is recommended that staff and members of the general public review written material such as the consent form and teaching material to test for ease of reading and clarity.

Limitations of the Study

One of the main limitations of the pilot study was the small sample size. Inferential statistics could not be calculated because of the inadequate sample size. Another key limitation was the randomization process used in this pilot. Adopting the same number sequencing process to be used in the larger study resulted in an unequal distribution of the interventions in the three groups. For example, only one subject was randomized to the Contisol G arm, three to saline, and five to no-intervention or control arm. An additional suggestion would be to adjust the research randomizing process for the pilot by including equal chances to be randomized into one of the three intervention groups based on the sample size calculated for the pilot. Because of the unequal distribution of interventions in the groups, it was difficult to compare and analyze the data.

Conducting this study in a setting with few professional nursing staff was another significant challenge. Much of the care of catheters was delegated to nursing attendants, whose training was limited to emptying a catheter bag and attaching and washing a leg bag. They were not trained to empty a full catheter bag based on the resident's need, to prevent the bag from touching the floor, or anchoring the catheter to the resident. Given the complex nature of the population in a long-term care setting, combined with the diverse range of practices in standard catheter care, many variables could not be controlled in this clinical setting. The range of catheter practices varied, as did interest in the study protocol and support for the research on the unit.

Lastly, although the study was conducted in a setting with a multicultural population and available interpreters, the study was limited to English-speaking residents. Restricting a study to English-speaking residents limited potential residents who have access to interpreters and further contributes to the under-representation of ethnic and minority group involvement and access to clinical research.

Conclusion

This pilot study, in preparation for a larger study, examined the process used to recruit subjects and test the procedures established (for use in the parent study) to compare Contisol G irrigations versus saline irrigations to standard catheter changes in subjects with a history of blocked catheters. It provided an effective means of testing planned procedures. The one-on-one recruitment strategy was found to be the most effective method of identifying potential subjects. The procedures used to compare the subjects were also effective. The overall management of blocked catheters remains a complicated issue, and the pilot revealed how important it is for nurses to be knowledgeable and skilled in this area. They need to be familiar with evidence-based practices in catheter care and with how to prevent and manage catheter-related problems to be able to make recommendations and decisions in teaching residents about their catheters and improving their care.

This study illustrates the intricacies involved in conducting a study in a clinical setting staffed with a high percentage of nonprofessional staff on a complex topic. The findings suggest that prepackaged irrigation systems could provide an economical and relatively efficient method of irrigating catheters if effective. The pilot offered an opportunity to examine the study design, the appropriateness of the tools and questionnaires selected for the data collection, the language content of the consent and educational material, the ease of use of the product (prepackaged irrigation solutions), and the recruitment process.

The main recommendations for further studies are: (a) An adequate sample size; (b) conduct research during regular seasons and avoid peak holiday periods such as summer vacations; (c) adjust the randomization process to the sample size; (d) plan additional time for unexpected delays and recruitment challenges in conducting clinical research in a nonacademic setting; (e) track potential subjects' catheter history, insertion pattern, changes, and care for a set period of time prior to starting the study; (f) use the MMSE that includes the education component, and add clinical judgment to the inclusion criteria; (g) add non–English-speaking subjects to the inclusion criteria (if an interpreter is available); (h) test the urine for haemoglobin, in addition to the pH, with the dipstick following each irrigation and record the results; (e) slice the catheter post-removal to visually confirm that the catheter blockage was caused by encrustations; (f) use a validated numerical scale or Likert scale to rate the comfort scores, and include a diagram of the human body to mark the location of any discomfort; (g) ensure that staff and members of the general public review the content and language of written material and comfort tools; (h) consider the use of weekly sequential irrigations rather than weekly single irrigations in a subsequent study; and (i) include a range limit for the age categories in the inclusion criteria.

Blockages in catheters and bypassing of urine are not only stressful for residents, but also place an extra burden on carers and additional demands on nursing time and healthcare resources. Extending the life of a catheter by irrigating it with Contisol G could potentially improve resident comfort and reduce nursing time. With an aging population and the increasing numbers of individuals with complex chronic illnesses who require long-term care, it is critical to conduct additional clinical research that can help to improve the care and quality of life for residents who require long-term IUCs, while also providing the most cost-effective approach to the treatment of blockages.

No generalizations can be made about the products utilized. The results are descriptive and intended only to aid in refinement of the parent study. Further research is required to determine whether using Contisol G is a cost-effective intervention to prolong catheter life compared to standard practice. Additional research is essential to determine whether individualized catheter care plans improve catheter care practices and enhance the use of evidence-based practices in clinical settings. The value of routine pH testing warrants further research to determine whether testing urine would be beneficial in determining who is at risk for catheter encrustations and blockages. In addition, future studies are needed to compare the use of weekly sequential irrigations with Contisol G in a clinical setting compared to weekly single irrigations, as well as additional clinical trials to determine how often irrigations should occur to reduce blockages.

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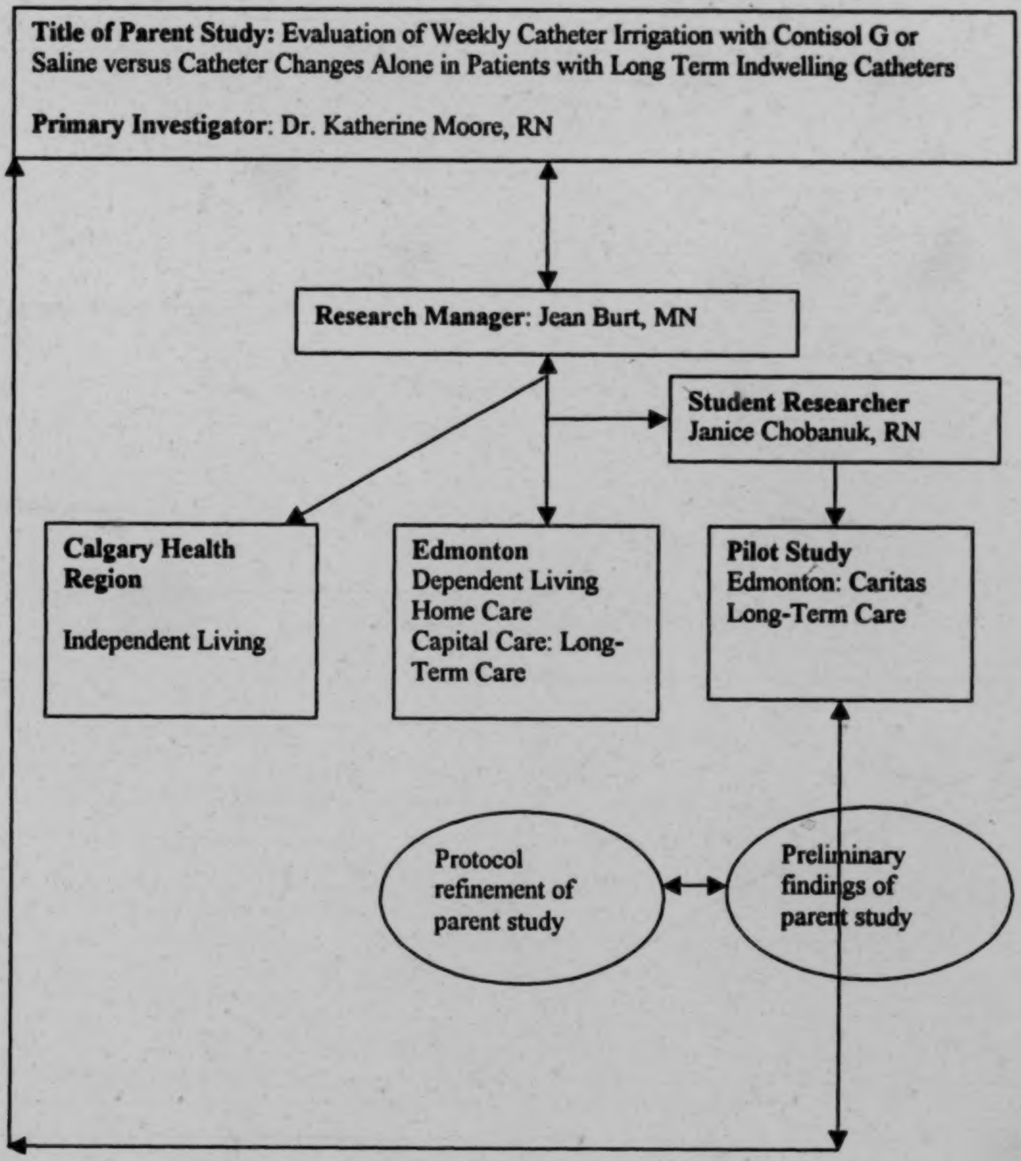
APPENDIX A:

RESEARCH CONTEXT FOR THE PILOT STUDY

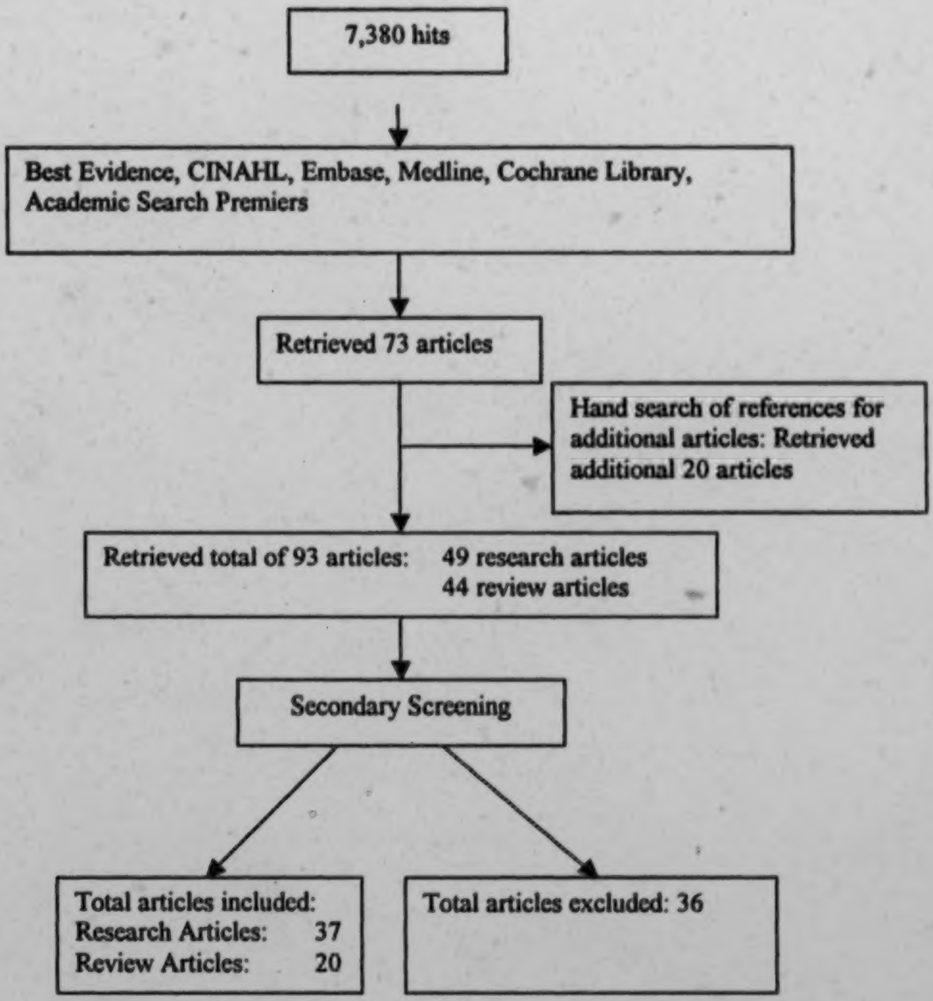
Appendix A: Research Context for the Pilot Study


Title of Parent Study: Evaluation of Weekly Catheter Irrigation with Contisol G or Saline versus Catheter Changes Alone in Patients with Long Term Indwelling Catheters
Primary Investigator: Dr. Katherine Moore, RN
Research Manager: Jean Burt, MN
Student Researcher
Janice Chobanuk, RN
Calgary Health Region
Independent Living
Edmonton
Dependent Living
Home Care
Capital Care: Long-Term Care
Pilot Study
Edmonton: Caritas
Long-Term Care
Protocol refinement of parent study
Preliminary findings of parent study

APPENDIX B:

SEARCH AND RETRIEVAL PROCESS FOR LITERATURE

Appendix B: Search and Retrieval Process for Literature


7,380 hits
Best Evidence, CINAHL, Embase, Medline, Cochrane Library, Academic Search Premiers
Retrieved 73 articles
Hand search of references for additional articles: Retrieved additional 20 articles
Retrieved total of 93 articles: 49 research articles
44 review articles
Secondary Screening
Total articles included:
Research Articles: 37
Review Articles: 20
Total articles excluded: 36

APPENDIX C:

CHART OF THE LITERATURE

Appendix C: Chart of the Literature

Irrigation solution	Author/year	Study design Study setting	Number of subjects Amount of solution Irrigation method Balloon size Size and type of catheter Frequency of irrigation	Outcome of study
Saline solution and noxythiolin	Elliot, Reid, Gopal Rao, Rigby, & Woodhouse, (1989)	Crossover prospective study Not described	9 subjects 30-60 mls Slow instillation (no description of method) Solution left in bladder up to 30 minutes No description of balloon size or catheter size/type irrigations every 2-6 weeks	Further urothelial damage occurred during bladder irrigations with each of these irrigation solutions as evidenced by increased urothelial cell exfoliation. The increased exfoliation suggests that irrigations may not only be ineffective but also may be damaging. The solutions were left in the bladder up to 30 minutes which may have contributed to the increased exfoliation. The physical force of the method of irrigation may have also caused damage to the compromised cell sheets. There was no information on the size of the catheter or size of the balloon which could also potentially affect the integrity of the urethelial cells. In this study 7 of 9 subjects received both types of solutions consequently making it difficult to compare the effect of each irrigation solution. There was not enough information to make a conclusion about the outcomes of using both solutions on the 7 subjects. The sample size was too small to make any generalizations to a larger population.

(table continues)

Irrigation solution	Author/year	Study design Study setting	Number of subjects Amount of solution Irrigation method Balloon size Size and type of catheter Frequency of irrigation	Outcome of study
Suby G, mandelic acid, and saline	Getliffe (1994)	Descriptive Laboratory study	Not on human subjects (4 experiments) 100 mls of solution Gentle instillation of prepackaged solutions over 90 seconds which was left in catheter/model bladder for 15 minutes # 18 cherriere catheter Irrigations were done after 114 hours	Synthetic urine was used in a model bladder in which saline irrigations were compared with Suby G and Mandelic acid. Suby G and Mandelic acid were found to be effective to reduce and eliminate encrustations. Normal saline was found to be less effective than the acidic solutions in reducing catheter encrustations. This laboratory study needs to replicated in a clinical setting in order to be able to generalize to human subjects. The data was only collected for 14 days which may have been too short a time period to determine if the effect of the intervention could be sustained over a longer period of time. The use of synthetic urine may have also had some impact on the results of this study.
Suby G	Getliffe, Hughes, & Le Claire (2000)	Descriptive Laboratory study	Not on human subjects (4 models of bladders) 100 mls and 50 mls of solution Gentle instillation of prepackaged solutions over a one minute time frame and left in catheter/model bladder for 15 minutes Hydrogel coated # 14 Foley catheter 15 mls of water inserted into a 10 ml balloon	An artificial bladder model with human urine was used in this study. This study was to compare a 100 ml instillation of Suby G to 50 mls of Suby G in reducing encrustations in an artificial bladder. There appeared to be no statistical difference between using the 100 or 50 mls of Suby G. Sequential irrigations with Suby G did dissolve more calcium and magnesium than a single irrigation which suggests the possibility of prolonging the catheter's life. Questions were raised regarding the need to leave the instillation fluid in the bladder for 15 minutes and if this time could be reduced. This laboratory study needs to be replicated in a clinical setting.

(table continues)

Irrigation solution	Author/year	Study design Study setting	Number of subjects Amount of solution Irrigation method Balloon size Size and type of catheter Frequency of irrigation	Outcome of study
Suby G and saline solution	Hesse, Nolde, Klump, Marklein, and Tuschewitzki (1992)	Descriptive Laboratory study	Not on human subjects 100 mls of solution daily 30 minute irrigations 18 French silicone-coated latex catheters 8 mls of distilled H20 inserted into the balloon	Daily irrigations with Suby G in a model with synthetic urine resulted in dissolution of 70% of crystal deposits. Saline only had a mechanical effect. A double irrigation before removal of crusted catheter completely cleared lumen. The use of synthetic urine rather than human urine may have had some impact on the outcomes of this study. This laboratory study needs to be replicated in a clinical setting.
Suby G, saline, and solution R	Kennedy, Brocklehurst, & Faragher (1992)	Crossover study Long-term care geriatric unit in 3 hospitals	25 patients randomized (14 out of 25 completed the study) 100 mls Irrigation was by gravity Solution left in place for 20-30 minutes Twice weekly irrigations No information on the size of balloon or size/type of catheters	There was a reduction of crystals for both Suby G and Solution R initially, but no difference between all 3 solutions after 3 weeks. There was less struvite crystals present in the returned acidic instillations but no reduction in the saline washout solution. Solution R produced the best results and Suby G the worst results. Higher percentage of blood cells were noted in the urine with use of Suby G and Solution R for irrigation solutions, however there had been no baseline measures of the subject's urine before this therapy was started. One patient developed frank hematuria with Solution R which stopped when Suby G was used as the irrigation solution. No explanation was provided why pressure had to be used for instilling the solutions in addition to gravity in some cases or the impact of this pressure. The sample size was too small for making any generalizations to a similar population at this time. *(table continues)*

Irrigation solution	Author/year	Study design Study setting	Number of subjects Amount of solution Irrigation method Balloon size Size and type of catheter Frequency of irrigation	Outcome of study
Citric acid maintenance solution (CMS)	McNicol (2003)	Descriptive controlled trial Community setting	4 patients (11 recruited) No information was provided on the amount of CMS solution used or which type of CMS solution was used in this study (Pre-packaged citric acid maintenance solution) No information on catheter size or balloon size or what solution was used in the balloon Daily irrigations over 12 weeks versus planned catheter changes and as needed catheter changes	Changing the catheter compared to the irrigation with CMS was shown to be more cost effective and had a lower incidence of infections compared to daily irrigations. There was some conflicting information in which nurses may have been performing bladder washouts rather than instillations as per the instructions on the CMS packaging. The sample size was too small to generalize to a similar population.
Saline	Muncie, Hoopes, Damron, Tenney, & Warren (1989)	Descriptive crossover design Hospital setting	23 patients (44 accrued) Randomized study 30 mls of solution in a syringe Daily irrigations Used syringe for irrigation, & the irrigation solution was pushed into catheter slowly 18 French silicone coated latex catheters 5 mls balloon with 7-20 mls of saline. Catheters with 30 mls balloon were used for some subjects.	Daily irrigations with saline compared to a no irrigation group showed no reduction in the incidence of obstructions, febrile periods and/or prevalence of bacteria. Concluded that the process was both time-consuming and costly. The overfilling of the 5 ml balloons, use of 30 ml balloons, use of saline in the catheter balloons (distilled water is typically used in balloons) may have contributed to urinary bypassing and subsequent blockages.

APPENDIX D:

POSTER

Appendix D: Poster

Pilot Nursing Study with University of Alberta

Volunteers with Indwelling Catheters Wanted!

Seeking residents with indwelling catheters willing to take part in a pilot research study on blockages in urinary catheters.

The goal of this study is to reduce or stop blockages from occurring. If you have problems with blocked catheters you may be able to enrol in this pilot. This study is part of a large study trying to find the best way to reduce or stop this problem for people such as yourself. The 3 methods being tested are: clearing the catheter with a mild acetic acid called Contisol every 7 days, clearing the catheter with a sterile salt water solution called Saline every 7 days or by inserting a new catheter when the old one gets blocked.

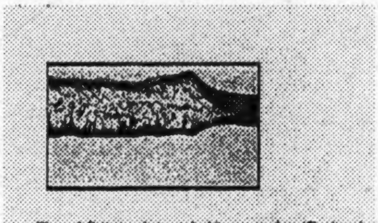


Figure 2 Catheter obstructed with encrustations (file photos)

Qualifications:

18 years of age or older

Have had an indwelling urinary catheter for a month

Have a history of blockages in your catheter

By participating you will:

Help to improve care of residents with urinary catheters that keep blocking up

If you are interested or have further questions please contact:

Call: Janice Chobanuk, Research Nurse

Pager: (780) 445-6913

Phone: (780) 482-8049

APPENDIX E:

RESEARCH STUDY INFORMATION FOR EGCCC NURSING STAFF

Appendix E: Research Study Information for EGCCC Nursing Staff

Title of Study*: Evaluation of Weekly Catheter Irrigations With Contisol G or Saline Versus Catheter Changes Alone in Patients with Long-Term Indwelling Catheters*

We are a team of nursing researchers from the University of Alberta. Dr. Katherine Moore is an expert in urology and catheter care. We are going to be recruiting residents from the EGCCC sites to participate in this study. It is hoped that outcomes from this study will show an increase in the length of time indwelling catheters remain unblocked by reducing the amount of crustations that cause blockage. Following is a brief outline of the responsibilities of persons involved in the study.

Research Nurse: Janice Chobanuk RN

- Provide inservices (D-E-N) for nursing staff prior to study beginning
- Obtain consent from residents who wish to participate in the study
- Explain study to the residents
- Insert the first catheter when a resident starts on the study
- Perform the catheter irrigations
- Conduct interviews with the residents
- Communicate with nursing staff, Managers, and Clinical Specialist
- Complete any required documentation
- Be available for any questions from nursing staff and families
- Provide study updates

EGCCC Nursing Staff:

- Inform the Research Nurse of potential residents for the study
- Provide a brief introduction to the resident/family about the study
- Remove blocked catheters & chart reason
- Insert a new study catheter (if indicated)
- Communicate with Research Nurse during site visits or as necessary (by telephone, e-mail, or fax)

We are looking forward to working with you on this nursing study.

Janice Chobanuk RN
Research Nurse **482-8049 or 445-6913** (pager)

Jean Burt
Project Coordinator
(780) 431-0130 jean.burt@nurs.ualberta.ca (790) 492-1541
fax: (780) 492-2551 cell phone: 905-3623

Katherine Moore PhD RN
Principal Investigator

APPENDIX F:

INVITATION TO PARTICIPATE AND LETTER OF INFORMED CONSENT

Appendix F: Invitation to Participate and Letter of Informed Consent

UNIVERSITY OF ALBERTA

Evaluation of catheter irrigations with Contisol G or saline compared to catheter changes alone in patients with long term indwelling catheters.

You are being asked to take part in a study on care of people with indwelling catheters.

Research Team

Katherine N. Moore, RN, PhD, University of Alberta (780) 492 1541
Kathleen Hunter, RN, GNP, University of Alberta
Lakshmi Puttagunta, MD, FRSC, University of Alberta

PURPOSE OF THIS STUDY: Many people with catheters have problems because the catheters block causing bladder spasms and urine leakage. What we need to know is whether we can control these problems if a nurse uses a special solution each week to irrigate the catheter.

To study the question of catheter blockage, we are randomly assigning people to one of three groups:

- your normal catheter care of regular changes,
- irrigation with sterile normal saline, or
- irrigation with a mild acidic solution called Contisol G.

You have an equal chance of being in any group.

STUDY PROCEDURE: If you would like to be in this study please call the research nurse, **Janice Chobanuk 482-8049 or 445-6913 (pager).** She will meet with you and explain the study and have you sign a consent form. Taking part in this study is entirely up to you. If you do take part, you do not have to answer any questions or discuss any subject in the interviews or questionnaires if you do not want to. You can drop out of the study at any time. If you drop out your care by any healthcare professional will not be affected.

The first visit will take about 30 minutes. The research nurse will visit when your catheter is changed. She will ask you some questions about satisfaction with the catheter. If you are in one of the irrigation groups, she will irrigate your catheter and bladder with 2 ounces of liquid. The liquid will be swished in and out of your catheter about 5 times. These visits will take about 20 minutes. You will be asked about comfort of the irrigation procedure right after the irrigation and 2 hours after the irrigation. The visits with the nurse will be one time a week.

RISKS: Many nurses irrigate out catheters to stop blockage. No one has reported any problems with this washing. Contisol G is used in many centers as an irrigation solution for catheters. We do not know of any problems or side effects with Contisol G but it is possible that the weak acidic solution could irritate the bladder. This might cause discomfort. If discomfort occurs, you can ask the nurse to stop using the solution.

BENEFITS: It may be helpful to you and your family to have the support of and access to Ms Burt, who is an experienced urology nurse. You and your caregiver may ask her any questions you have during the study.

You will receive the catheter irrigations and catheter changes at no cost.

CONFIDENTIALITY: All information will be held confidential (or private), except when professional codes of ethics or legislation (or the law) requires reporting. Your name and your doctor's name will not appear in any reports. All records concerning you will be stored in a locked filing cabinet to which only the researchers have access. These records will be kept in a locked cabinet separate from consent forms or code list for at least five years after the study ends.

By signing the consent form you give permission to the study staff to access any personally identifiable health information which is under the custody of other healthcare professionals as deemed necessary for the conduct of the research.

The information from this study may be published or presented at conferences, but your name or any material that identifies you will not be used.

QUESTIONS OR CONCERNS: If you have questions or concerns about this research study, you or your family can call the Research Nurse, Janice, at **482-8049** or **445-6913 (pager),** Dr. Moore at 492 -1541, or contact the Concerns Person at EGCCC, Caritas at 482- 8496 (Averil Suriyakumaran).

UNIVERSITY OF ALBERTA

CONSENT FORM

Evaluation of catheter irrigations with Contisol G or saline versus catheter changes alone in patients with long term indwelling catheters.

Research Team

Katherine N. Moore, RN, PhD, University of Alberta
Kathleen Hunter, RN, GNP, University of Alberta
Lakshmi Puttagunta, MD, FRSC, University of Alberta

Do you understand that you have been asked to be in a research study?
Yes No

Have you read and received a copy of the attached Information Sheet?
Yes No

Do you understand the benefits and risks involved in taking part in this research study?
Yes No

Have you had an opportunity to ask questions and discuss this study?
Yes No

Do you understand that you are free to refuse to participate or withdraw from the study at any time? You do not have to give a reason and it will not affect your care.
Yes No

Has the issue of confidentiality/anonymity been explained to you? Do you understand who will have access to your records, including personally identifiable health information?
Yes No

This study was explained to me by:

Date

I agree to take part in this study.

Signature of Research Participant Printed Name Date

Signature of Witness Printed Name Date

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Principal Investigator or Designee Printed Name Date

QUESTIONS: If you have questions about this research study, you or your family can call the Research Nurse Janice Chobanuk at 445-6913 (Pager) or (780) 482-8049 (W) or or Dr. Moore at 492-1541.

CONCERNS: If you have any concerns about any aspect of this study, you may contact Averil_Suriyakumaran, Acting Director of Edmonton General Continuing Care Centre at (780) 482-8496 (W) or 445-3296 (Pager) or the Research Office at the Caritas Health Group at (780) 930-5274. This contact person and the research office have no affiliation with this study.

APPENDIX G:

QUESTIONNAIRE: CATHETER SURVEILLANCE

Appendix G: Questionnaire: Catheter Surveillance

Subject Number:

Date:

Please answer the following questions about your catheter change.

How would you rate:

1. Your bladder comfort before catheter change?

   Acceptable Unacceptable

2. Comfort when the catheter was inserted?

   Good Acceptable Unacceptable

3. Comfort after the catheter was in place for 15 minutes?

   Good Acceptable Unacceptable

4. Comfort 2 hours after the catheter had been changed?

   Good Acceptable Unacceptable

5. How satisfied are you with your current catheter program?

   Good Acceptable Unacceptable

Comments:

Leukocytes _______

Nitrites _________

pH ____________

Blood ____________

APPENDIX H:

QUESTIONNAIRE: CATHETER IRRIGATION

Appendix H: Questionnaire: Catheter Irrigation

Subject Number:

Date:

Please answer the following questions about the irrigation you have just received.

How would you rate:

1. Your bladder comfort before irrigation?

   Acceptable Unacceptable

2. Comfort when the solution was felt in the bladder?

   Good Acceptable Unacceptable

3. Comfort after having the solution swished in and out of your catheter 5 times over several minutes?

   Good Acceptable Unacceptable

4. Comfort 2 hours after the irrigation was completed?

   Good Acceptable Unacceptable

5. How satisfied are you with your current catheter program?

   Good Acceptable Unacceptable

6. Would you recommend the bladder irrigation?

   Yes No

Pre Flush

Leukocytes ________

Nitrites __________

Post flush pH

pH ________ ___________

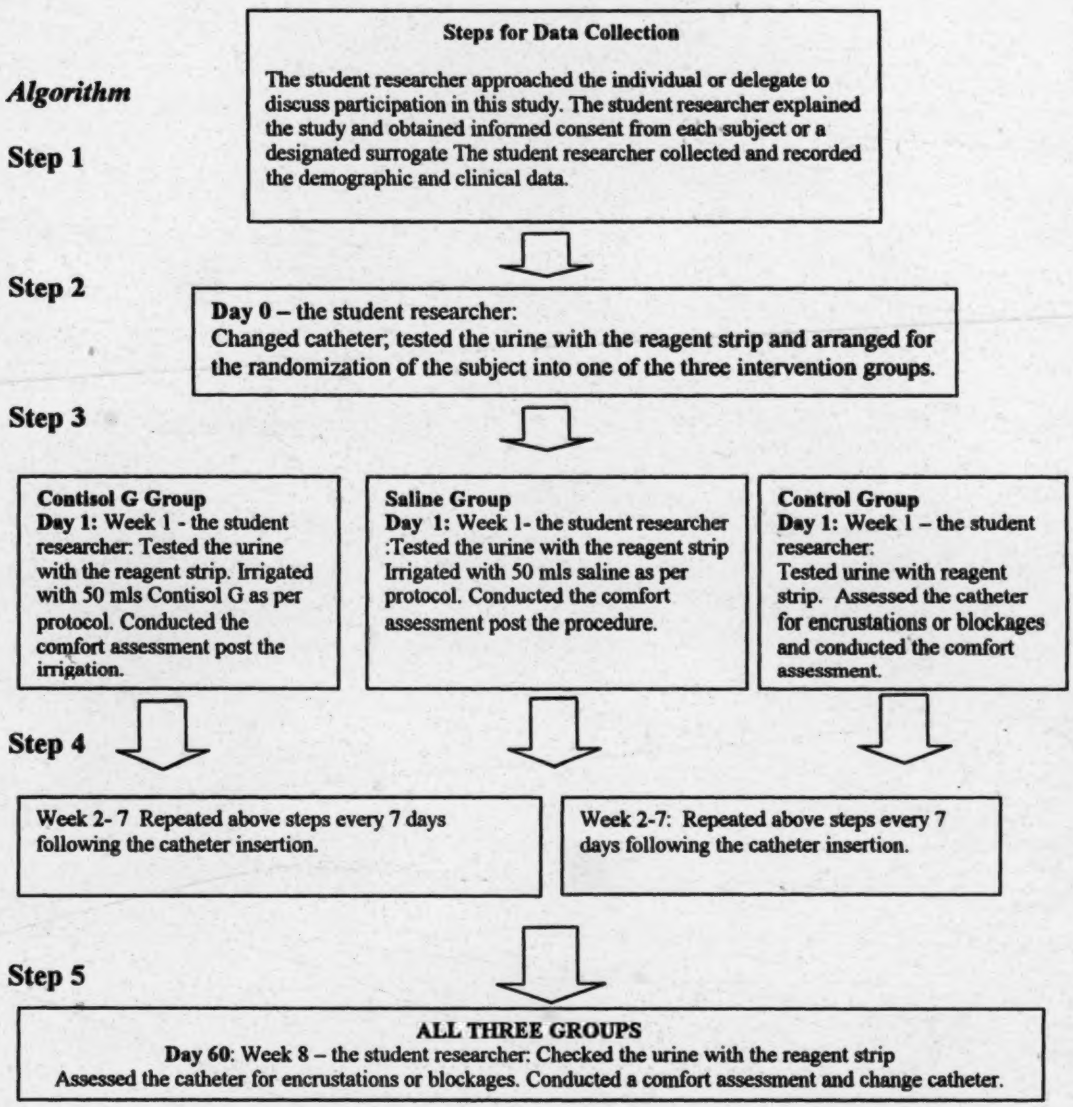
Blood ____________

Comments:

APPENDIX I:

STEPS IN DATA COLLECTION

Appendix I: Steps in Data Collection



Algorithm

Step 1

Steps for Data Collection

The student researcher approached the individual or delegate to discuss participation in this study. The student researcher explained the study and obtained informed consent from each subject or a designated surrogate The student researcher collected and recorded the demographic and clinical data.

Step 2

Day 0 – the student researcher:
Changed catheter; tested the urine with the reagent strip and arranged for the randomization of the subject into one of the three intervention groups.

Step 3

Contisol G Group
Day 1: Week 1 - the student researcher: Tested the urine with the reagent strip. Irrigated with 50 mls Contisol G as per protocol. Conducted the comfort assessment post the irrigation.

Saline Group
Day 1: Week 1- the student researcher :Tested the urine with the reagent strip Irrigated with 50 mls saline as per protocol. Conducted the comfort assessment post the procedure.

Control Group
Day 1: Week 1 – the student researcher:
Tested urine with reagent strip. Assessed the catheter for encrustations or blockages and conducted the comfort assessment.

Step 4

Week 2- 7 Repeated above steps every 7 days following the catheter insertion.

Week 2-7: Repeated above steps every 7 days following the catheter insertion.

Step 5

ALL THREE GROUPS
Day 60: Week 8 – the student researcher: Checked the urine with the reagent strip
Assessed the catheter for encrustations or blockages. Conducted a comfort assessment and change catheter.